New Jersey Office of the Attorney General

Division of Consumer Affairs
Enforcement Bureau/ Drug Control Unit
Controlled Dangerous Substances
Statutes and Regulations

AS OF APRIL 2005 INTERNET - 4/05

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Controlled Dangerous Substances

45:1-1. Persons entitled to practice, etc. under former laws unaffected

Any person now entitled to practice any profession or to engage in any occupation, governed or egulated by the provisions of this title by virtue of any prior law, shall continue to be entitled to practice or engage in the same, notwithstanding the enactment of this title, and the validity of any license or other uthorization to practice any such profession or to engage in any such occupation, heretofore issued to any person under any prior law, or of any proceeding pending to obtain such a license or authorization shall not be affected by the enactment of this title but all such persons shall in all other respects be subject to the provisions of this title.

45:1-2. Repealed by L.1971, c. 60,§ 5, eff. March 25, 1971

45:1-2.1. Professional boards and commissions; application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the New Jersey Real Estate Commission, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, the State Board of Public Movers and Warehousemen and the State Board of Physical Therapy Examiners.

45:1-2.2. Appointment of members by governor; public members; member from department in executive branch; quorum; vote necessary for action

a. All members of the several professional boards and commissions shall be appointed by the Governor in the manner prescribed by law; except in appointing members other than those appointed pursuant to subsection b. or subsection c., the Governor shall give due consideration to, but shall not be bound by, recommendations submitted by the appropriate professional organizations of this State.

b. In addition to the membership otherwise prescribed by law, the Governor shall appoint in the same manner as presently prescribed by law for the appointment of members, two additional members to represent the interests of the public, to be known as public members, to each of the following boards and commissions: The New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological

Examiners, the New Jersey Real Estate Commission, the State Board of ShorthandReporting, the State Board of Social Work Examiners, and the State Board of Veterinary Medical Examiners, and one additional public member to each of the following boards: the Board of Examiners of Electrical Contractors, the State Board of Marriage and Family Therapy Examiners, the State Board of Examiners of Master Plumbers, and the State Real Estate Appraiser Board. Each public member shall be appointed for the term prescribed for the other members of the board or commission and until the appointment of his successor. Vacancies shall be filled for the unexpired term only. The Governor may remove any such public member after hearing, for misconduct, incompetency, neglect of duty or for any other sufficient cause.

No public member appointed pursuant to this section shall have any association or relationship with the profession or a member thereof regulated by the board of which he is a member, where such association or relationship would prevent such public member from representing the interest of the public. Such a relationship includes a relationship with members of one's immediate family; and such association includes membership in the profession regulated by the board. To receive services rendered in a customary client relationship will not preclude a prospective public member from appointment. This paragraph shall not apply to individuals who are public members of boards on the effective date of this act.

It shall be the responsibility of the Attorney General to insure that no person with the aforementioned association or relationship or any other questionable or potential conflict of interest shall be appointed to serve as a public member of any board regulated by this section. Where a board is required to examine the academic and professional credentials of an applicant for licensure or to test such applicant orally, no public member appointed pursuant to this section shall participate in such examination process; provided, however, that public members shall be given notice of and may be present at all such examination processes and deliberations concerning the results thereof, and, provided further, that public members may participate in the development and establishment of the procedures and criteria for such examination processes.

c. The Governor shall designate a department in the Executive Branch of the State Government which is closely related to the profession or occupation regulated by each of the boards or commissions designated in section 1 of P.L.1971, c. 60 (C. 45:1-2.1) and shall appoint the head of such department, or the holder of a designated office or position in such department, to serve without compensation at the pleasure of the Governor as a member of such board or commission.

d. A majority of the voting members of such boards or commissions shall constitute a quorum thereof and no action of any such board or commission shall be taken except upon the affirmative vote of a majority of the members of the entire board or commission.

45:1-2.3. Qualifications; rights and duties

Such additional members:

a. Need not meet the educational and professional requirements for membership on such boards or commissions as provided in the several statutes establishing such boards and commissions; and b. Shall be voting members subject to the same rights, obligations and duties as other members of their respective boards or commissions.

45:1-2.4. Effect of act on term of member in office

Nothing in this act shall affect the right of a board or commission member in office on the effective date of this act to continue to serve for the term for which he was appointed.

45:1-2.5. Compensation and reimbursement of expenses of members; executive secretaries; compensation and terms of employment; offices and meeting places

With respect to the boards or commissions designated in section 1 of P.L.1971, c. 60 (C.45:1-2.1), except as otherwise provided in subsection d. of this section, and notwithstanding the provisions of any other law:

a. The officers and members shall be compensated on a per diem basis in the amount of $25.00 or an amount to be determined by the Attorney General, with the approval of the State Treasurer, but not to exceed $100.00 per diem or $2,500.00 annually, and shall be reimbursed for actual expenses reasonably incurred in the performance of their official duties. Such moneys shall be paid according to rules and regulations promulgated by the Attorney General.

b. The executive secretary shall receive such salary as shall be determined by the appointing authority within the limits of available appropriations and shall serve at its pleasure. Any such executive secretary who holds a certificate, license or registration issued by the board or commission by which he is employed shall not during such employment be permitted to engage in any profession or occupation regulated by the board or commission.

c. The head of the department to which such board or commission is assigned shall maintain within any public building, whether owned or leased by the State, suitable quarters for the board's or commission's office and meeting place, provided that no such office or meeting place shall be within premises owned or occupied by an officer or member of such board or commission.

d. The compensation schedule for members of boards and commissions provided in subsection a. of this section shall not apply to the members of the New Jersey Real Estate Commission, who shall be compensated pursuant to R.S.45:15-6 or to members of the State Board of Medical Examiners who shall receive compensation of $150 per diem.

45:1-2.6. Inapplicability of act to rights under civil service or any pension law or retirement system

Nothing in this act shall deprive any person of any tenure rights or of any right or protection provided him by Title 11 of the Revised Statutes, Civil Service,[1] or any pension law or retirement system.

[1]Now title 11A.

45:1-3. Expenses of boards paid from income; surplus paid to state treasurer; accounts

Each member of the boards mentioned in section 45:1-2 1 of this title shall be entitled to his actual traveling and other expenses incurred in the performance of his duties, which sum shall be paid from the license fees and other sources of income of such boards. Such boards shall also be entitled to expend from their income such sums as shall be necessary to defray all proper expenses incurred by them in the performance of their duties, including the compensation of any of their officers or agents whom they are authorized to compensate. Such boards, if authorized to collect an annual registration or license fee from persons licensed by them, may retain in their treasuries the fees so collected and use

the same for the purpose of defraying the expenses of securing evidence against and prosecuting persons violating the provisions of the laws with the enforcement of which they are charged, or, in case the revenue of the boards from other sources shall be insufficient to pay the salary of their secretaries and their other expenses, such fees may be expended for such purposes. Such boards shall be entitled to retain, in addition to the above, at least one hundred dollars in their treasuries for the purpose of preparing and holding their examinations. On or before October thirty-first in each year such boards shall pay to the state treasurer all moneys remaining in their treasuries, except as above stated, which sum, when so paid, shall form a part of the state fund. Such boards shall keep accurate accounts of their receipts and expenditures, which accounts shall be subject to audit by the state comptroller.

[1]Repealed; see, now, §§ 45:1-2.1, 45:1-2.2.

45:1-3.1. Application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board , the New Jersey Cemetery Board, the State Board of Social Work Examiners and the State Board of Physical Therapy Examiners.

45:1-3.2. Charges for examinations, licensures and other services; establishment or change by rule; standards

Notwithstanding the provisions of Title 45 of the Revised Statutes or any other law to the contrary, any board or commission named in section 1 of this supplementary act [1] may by rule establish, prescribe or change the charges for examinations, licensures and other services it performs, which rule shall first be approved by the head of the department to which such board or commission is assigned and shall be adopted in accordance with the provisions of the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B-1).

Any board's or commission's charges established, prescribed or changed pursuant to this section shall be established, prescribed or changed to such extent as shall be necessary to defray all proper expenses incurred by the board or commission in the performance of its duties but such charges shall not be fixed at a level that will raise amounts in excess of the amount estimated to be so required.

[1]N.J.S.A. § 45:1-3.1.

45:1-3.3. Administrative fees charged by boards; modification

The Director of the Division of Consumer Affairs may by rule establish, prescribe, or modify administrative fees charged by boards in accordance with the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B-1 et seq.). For purposes of this section, ''administrative fees'' are charges assessed to licensees, registrants or holders of certificates, as the case may be, for board functions that are not unique to a particular board but are uniform throughout all boards. Administrative fees include, but are

not limited to, fees for a duplicate or replacement license, certification or registration, late renewal fee, license reinstatement fee, and the fee for processing change of address.

45:1-4. Salary of secretary

The secretary of each of the boards mentioned in section 45:1-2 [1] of this title, whether or not a member thereof, shall be entitled to receive such reasonable salary or compensation for his services as secretary as shall be fixed by such boards, which shall be paid by the boards from their receipts, unless an appropriation is made for the expenses of such boards, in which case the same shall be paid from such appropriation.

[1]Repealed. See, now, §§ 45:1-2.1, 45:1-2.2.

45:1-5, 45:1-6. Repealed by L.1979, c. 432, § 4, eff. Feb. 14, 1980

45:1-7. Professional or occupational licenses or certificates of registration; duration; expiration; exceptions; fees

Notwithstanding any of the provisions of Title 45 of the Revised Statutes or of any other law to the contrary, all professional or occupational licenses or certificates of registration, except such licenses or certificates issued to real estate brokers or salesmen pursuant to chapter 15 of Title 45, which prior to the effective date of this act were issued for periods not exceeding one year and were annually renewable, shall, on and after the effective date of this act, be issued for periods of two years and be biennially renewable, except that licenses and business permits issued to electrical contractors and certificates of registration issued to qualified journeymen electricians pursuant to chapter 5A of Title 45 shall be issued for periods of three years and be triennially renewable; provided, however, the boards or commissions in charge of the issuance or renewal of such licenses or certificates may, in order to stagger the expiration dates thereof, provide that those first issued or renewed after the effective date of this act, shall expire and become void on a date fixed by the respective boards or commissions, not sooner than six months nor later than 29 months, after the date of issue.

The fees for the respective licenses and certificates of registration issued pursuant to this act for periods of less or greater than one year shall be in amounts proportionately less or greater than the fees established by law.

45:1-7.1. Application to holders of professional or occupational licenses

a. Notwithstanding any other act or regulation to the contrary, the provisions of this section and sections 6 and 7 of P.L.1999, c. 403 (C.45:1-7.2 et al.) shall apply to every holder of a professional or occupational license or certificate of registration or certification issued or renewed by a board specified in section 2 of P.L. 1978, c. 73 (C.45:1-15), who seeks renewal of that license or certificate.

b. Every holder of a professional or occupational license or certificate of registration or certification, issued or renewed by a board specified in section 2 of P.L.1978, c. 73 (C.45:1-15), who seeks renewal shall submit a renewal application and pay a renewal fee prior to the date of expiration of the license or certificate of registration or certification. If the holder does not renew the license or certificate prior to its expiration date, the holder may renew it within 30 days of its expiration date by submitting a renewal application and paying a renewal fee and a late fee. Any professional or occupational license or certificate of registration or certification not renewed within 30 days of its expiration date shall be suspended without a hearing.

c. Any individual who continues to practice with an expired license or certificate of registration or certification after 30 days following its expiration date shall be deemed to be engaged in unlicensed practice of the regulated profession or occupation, even if no notice of suspension has been provided to the individual.

d. A professional or occupational license or certificate of registration or certification suspended pursuant to this section may be reinstated within five years following its date of expiration upon submission of a renewal application and payment of an additional reinstatement fee. An applicant seeking reinstatement of a license or certificate suspended pursuant to this section more than five years past its expiration date shall successfully complete the examination required for initial licensure, registration or certification and submit a renewal application and payment of an additional reinstatement fee.

e. A board specified in section 2 of P.L. 1978, c. 73 (C. 45:1-15) shall send a notice of renewal to each of its holders of a professional or occupational license or certificate of registration or certification, as applicable, at least 60 days prior to the expiration of the license or certificate. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

45:1-7.2. Reinstatement

A board may reinstate the professional or occupational license or certificate of registration or certification of an applicant whose license or certificate has been suspended pursuant to section 5 of P.L.1999, c. 403 (C.45:1-7.1), provided that the applicant otherwise qualifies for licensure, registration or certification and submits the following upon application for reinstatement:

a. Payment of all past delinquent renewal fees;

b. Payment of a reinstatement fee;

c. An affidavit of employment listing each job held during the period of suspended license, registration or certification which includes the names, addresses, and telephone numbers of each employer; and d. If applicable, satisfactory proof that the applicant has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license or certificate of registration or certification.

45:1-7.3. Renewal applications

a. Renewal applications for all professional or occupational licenses or certificates of registration or certification shall provide the applicant with the option of either active or inactive renewal. A renewal applicant electing to renew as inactive shall not engage in professional or occupational practice within the State.

b. An applicant who selects the inactive renewal option shall remain on inactive status for the entire renewal period unless, upon application to the board, the board permits the inactive applicant to return to active status provided such applicant presents satisfactory proof that he has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license, registration or certification, if applicable. The continuing education hours or credits shall be completed by the applicant within three years prior to the date of application for the return to active status, unless otherwise provided by board rule.

45:1-8. Contractors; application of § 45:1-9

The provisions of this act apply to the following classes of contractors:

a. Tree experts, certified pursuant to P.L.1940, c. 100 (C. 13:1-28 et seq.[1]);

b. Home repair contractors, licensed pursuant to P.L.1960, c. 41 (C. 17:16C-62 et seq.);

c. Electrical contractors, licensed pursuant to P.L.1962, c. 162 (C. 45:5A-1 et seq.);

d. Master plumbers, licensed pursuant to P.L.1968, c. 362 (C. 45:14C-1 et seq.);

e. Well drillers, licensed pursuant to P.L.1947, c. 377 (C. 58:4A-5 et seq.); and

f. Any class of contractors who hereafter are licensed by the State.

[1]Renumbered C. 45:15C-1 to 45:15C-10.

45:1-9. Indication of license or certificate number on contracts, bids and advertisements

Any contractor licensed by the State shall indicate his license or certificate number on all contracts, subcontracts, bids and all forms of advertising as a contractor.

45:1-10. Disclosure of laboratory payments on bills to patients and third party payors

It shall be unlawful for any person licensed in the State of New Jersey to practice medicine or surgery, dentistry, osteopathy, podiatry or chiropractic to agree with any clinical, bio-analytical or hospital laboratory, wheresoever located, to make payments to such laboratory for individual tests, combination of tests, or test series for patients unless such person discloses on the bills to patients and third party payors the name and address of such laboratory and the net amount or amounts paid or to be paid to such laboratory for individual tests, combination of tests or test series.

45:1-10.1. Claims for third party payment; licensed health care professional ; responsibility for filing

Effective 12 months after the adoption of regulations establishing standard health care enrollment and claim forms by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23), a health care professional licensed pursuant to Title 45 of the Revised Statutes is responsible for filing all claims for third party payment, including claims filed on behalf of the licensed professional's patient for any health care service provided by the licensed professional that is eligible for third party payment, except that at the patient's option, the patient may file the claim for third party payment.

a. In the case of a claim filed on behalf of the professional's patient, the professional shall file the claim within 60 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23).

b. In the case of a claim in which the patient has assigned his benefits to the professional, the professional shall file the claim within 180 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30-23). If the professional does not file the claim within 180 days of the last date of service for a course of treatment, the third party payer shall reserve the right to deny payment of the claim, in accordance with regulations established by the Commissioner of Banking and Insurance, and the professional shall be prohibited from seeking any payment directly from the patient.

(1) In establishing the standards for denial of payment, the Commissioner of Banking and Insurance shall consider the good faith use of information provided by the patient to the professional with respect to the identity of the patient's third party payer, delays in filing a claim related to coordination of benefits between third party payers and any other factors the commissioner deems appropriate, and, accordingly, shall define specific instances where the sanctions permitted pursuant to this subsection shall not apply.

(2) A professional who fails to file a claim within 180 days and whose claim for payment has been denied by the third party payer in accordance with this subsection may, in the discretion of a judge of the Superior Court, be permitted to refile the claim if the third party payer has not been substantially prejudiced thereby. Application to the court for permission to refile a claim shall be ma de within 14 days of notification of denial of payment and shall be made upon motion based upon affidavits showing sufficient reasons for the failure to file the claim with the third party payer within 180 days.

c. The provisions of this section shall not apply to any claims filed pursuant to P.L.1972, c. 70 (C.39:6A-1 et seq.).

d. A health care professional who violates the provisions of subsection a. of this section may be subject to a civil penalty of $250 for each violation plus $50 for each day after the 60th day that the provider fails to submit a claim. The penalty shall be sued for and collected by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to ''the penalty enforcement law,''

45:1-11. Violations; penalty

Any person violating this act shall be guilty of a misdemeanor.

45:1-12. Podiatrist, optometrist or psychologist or professional service corporation; charge for completion of claim form for health insurance; fine; collection and enforcement

No podiatrist, optometrist or psychologist and no professional service corporation engaging in the practice of podiatry, optometry or psychology in this State shall charge a patient an extra fee for services rendered in completing a medical claim form in connection with a health insurance policy. Any person violating this act shall be subject to a fine of $100.00 for each offense.

Such penalty shall be collected and enforced by summary proceedings pursuant to the Penalty Enforcement Law (N.J.S. 2A:58-1 et seq.). The Superior Court and municipal court shall have juris diction within its territory of such proceedings. Process shall be either in the nature of a summons or warrant and shall issue in the name of the State, upon the complaint of the State Board of Medical Examiners with respect to podiatrists, the New Jersey State Board of Optometry for optometrists or the State Board of Psychological Examiners for psychologists.

45:1-13. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:1-14. Legislative findings and declarations; liberal construction of act

The Legislature finds and declares that effective implementation of consumer protection laws and the administration of laws pertaining to the professional and occupational boards located within the Division of Consumer Affairs require uniform investigative and enforcement powers and procedures and uniform standards for license revocation, suspension and other disciplinary proceedings by such boards. This act is deemed remedial, and the provisions hereof should be afforded a liberal construction.

45:1-15. Boards and professions or occupations regulated by or through such boards; application of act

The provisions of this act shall apply to the following boards and all professions or occupations egulated by, through or with the advice of those boards: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, the State Board of Physical Therapy Examiners, the Professional Counselor Examiners Committee, the New Jersey Cemetery Board, the Orthotics and Prosthetics Board of Examiners, the Occupational Therapy Advisory Council, the Electrologists Advisory Committee, the Alcohol and Drug Counselor Committee, the Fire Alarm, Burglar Alarm, and Locksmith Advisory Committee, the Home Inspection Advisory Committee, the Massage, Bodywork and Somatic Therapy Examining Committee, and the Audiology and Speech-Language Pathology Advisory Committee.

45:1-15.1. Rules and regulations

Consistent with their enabling acts, P.L.1978, c. 73 (C.45:1-14 et seq.) and the ‘‘Administrative Procedure Act,’’ P.L.1968, c . 410 (C.52:14B-1 et seq.), the boards and others set forth in section 2 of P .L.1978, c. 73 (C.45:1-15) are authorized to adopt rules and regulations to serve the public health, safety and welfare.

45:1-16. Definitions

As used within this act the following words or terms shall have the indicated definition unless the context clearly indicates otherwise. ‘‘Board’’ means any professional or occupational licensing board designated in section 2 of this act.[1] ‘‘Director’’ means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

‘‘Person’’ means any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trust thereof.

[1] N.J.S.A. § 45:1-15.

45:1-17. Powers of Attorney General to implement act and administer law enforcement activities of boards

In implementing the provisions of this act and administering the law enforcement activities of those professional and occupational boards located within the Division of Consumer Affairs, the Attorney General may:

a. After advice to the board or boards in question of his intent to proceed under this section, and the specific action he intends to take, and the failure of such board or boards to take steps in accordance with the advice of the Attorney General within 30 days of receipt of such advice,

promulgate rules and regulations consistent with the provisions of this act and the Administrative Procedure Act, P.L.1968, c. 410 (C. 52:14B-1 et seq.) governing the procedure for administrative hearings before all boards within the Division of Consumer Affairs. Such rules and regulations shall govern administrative complaints, answers thereto, issuance of subpenas, appointment of hearing examiners, adjournments, submission of proposed findings of fact and conclusions of law, the filing of briefs, and such other procedural aspects of administrative hearings before the boards as the Attorney General may deem necessary; provided, however, nothing herein authorized shall be construed to require the Attorney General to promulgate rules regarding prehearing investigative procedures.

b. After advice to the board or boards in question of his intent to proceed under this section, and the specific action he intends to take, and the failure of such board or boards to take steps in accordance with the advice of the Attorney General within 30 days of receipt of such advice, promulgate substantive rules and regulations consistent with the provisions of any statute governing the activities of any licensing agency, board or committee located within the Division of Consumer Affairs, which shall be limited to disciplinary matters and arbitrary restrictions on initial licensure. In addition to promulgating such rules and regulations, the Attorney General may direct that any proposed or existing regulation be amended, abandoned or repealed. Prior to the final adoption of any regulation affecting the activities of any professional or occupational licensing agency, board or committee located within the division and prior to the issuance of any directive to amend, abandon or repeal any regulation, the Attorney General or his designee shall first consult with the agency, board or committee whose activities are affected regarding the proposed action.

c. After a full consideration of all relevant facts and the applicable law, may direct the initiation of any appropriate enforcement action by a professional or occupational licensing board or set aside, modify or amend, as may be necessary, any action or decision of a licensing agency, board or committee located within the Division of Consumer Affairs; provided, however, no such action shall be directed by the Attorney General in reviewing the action or decision of an agency, board or committee unless such action or decision is contrary to applicable law.

45:1-18. Investigative powers of boards, director or attorney general

Whenever it shall appear to any board, the director or the Attorney General that a person has engaged in, or is engaging in any act or practice declared unlawful by a statute or regulation administered by such board, or when the board, the director or the Attorney General shall deem it to be in the public interest to inquire whether any such violation may exist, the board or the director through the Attorney General, or the Attorney General acting independently, may exercise any of the following investigative powers:

a. Require any person to file on such form as may be prescribed, a statement or report in writing under oath, or otherwise, as to the facts and circumstances concerning the rendition of any service or conduct of any sale incidental to the discharge of any act or practice subject to an act or regulation administered by the board;

b. Examine under oath any person in connection with any act or practice subject to an act or regulation administered by the board;

c. Inspect any premises from which a practice or activity subject to an act or regulation administered by the board is conducted;

d. Examine any goods, ware or item used in the rendition of a practice or activity subject to an act or regulation administered by the board;

e. Examine any record, book, document, account or paper prepared or maintained by or for any professional or occupational licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in practices subject to an act or regulation administered by the board. Nothing in this subsection shall require the notification or consent of the person to whom the record, book, account or paper pertains, unless otherwise required by law;

f. For the purpose of preserving evidence of an unlawful act or practice, pursuant to an order of the Superior Court, impound any record, book, document, account, paper, goods, ware, or item used, prepared or maintained by or for any board licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in a practice or activity subject to an act or regulation administered by the board. In such cases as may be necessary, the Superior Court may, on application of the Attorney General, issue an order sealing items or material subject to this subsection; and

g. Require any board licensee, permit holder or registered or certified person to submit to an assessment of skills to determine whether the board licensee, permit holder or registered or certified person can continue to practice with reasonable skill and safety. In order to accomplish the objectives of this act or any act or regulation administered by a board, the Attorney General may hold such investigative hearings as may be necessary and the board, director or Attorney General may issue subpoenas to compel the attendance of any person or the production of books, records or papers at any such hearing or inquiry.

45:1-19. Failure or refusal to file statement or report, refusal of access to premises or failure to obey subpena; penalty

If any person shall fail or refuse to file any statement or report or refuse access to premises from which a licensed profession or occupation is conducted in any lawfully conducted investigative matter or fail to obey a subpena issued pursuant to this act, the Attorney General may apply to the Superior Court and obtain an order:

a. Adjudging such person in contempt of court; or

b. Granting such other relief as may be required; or

c. Suspending the license of any such person unless and until compliance with the subpena or investigative demand is effected.

45:1-20. Compelling testimony or production of book, paper or document; immunity from prosecution

If any person shall refuse to testify or produce any book, paper, or other document in any proceeding under this act for the reason that the testimony or evidence, documentary or otherwise, required of him may tend to incriminate him, convict him of a crime, or subject him to a penalty or forfeiture, and shall, notwithstanding, be directed to testify or to produce such book, paper, or document by the Attorney General, he shall comply with such direction.

A person who is entitled by law to, and does assert such privilege, and who complies with such direction of the Attorney General shall not thereafter be prosecuted or subjected to any penalty or forfeiture in any criminal proceeding which arises out of and relates to the subject matter of the pro-

ceeding. No person so testifying shall be exempt from prosecution or punishment for perjury or false swearing committed by him in giving such testimony or from any civil or administrative action arising from such testimony.

45:1-21. Grounds for refusal to admit to examination or denial, suspension or revocation of any certificate, registration or license; definitions

A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or misrepresentation;

b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

d. Has engaged in repeated acts of negligence, malpractice or incompetence;

e. Has engaged in professional or occupational misconduct as may be determined by the board;

f. Has been convicted of, or engaged in acts constituting, any crime or offense involving moral turpitude or relating adversely to the activity regulated by the board. For the purpose of this subsection a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, agency or authority for reasons consistent with this section;

h. Has violated or failed to comply with the provisions of any act or regulation administered by the board;

i. Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;

j. Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with, such applications, required to be filed with the Department of Environmental Protection;

k. Has violated any provision of P.L.1983, c. 320 (C.17:33A-1 et seq.) or any insurance fraud prevention law or act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L.1983, c. 320 (C.17:33A-1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under that act against the applicant or holder;

l. Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subsection, the term ''presently'' means at this time or any time within the previous 365 days;

m. Has prescribed or dispensed controlled dangerous substances indiscriminately or without good cause, or where the applicant or holder knew or should have known that the substances were to be used for unauthorized consumption or distribution;

n. Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the board, or aided and abetted an unlicensed person or entity in performing such an act;

o. Advertised fraudulently in any manner.

The division is authorized, for purposes of facilitating determinations concerning licensure eligibility, to require the fingerprinting of each applicant in accordance with applicable State and federal laws, rules and regulations. Each applicant shall submit the applicant's name, address, and written consent to the director for a criminal history record background check to be performed. The division is authorized to receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation. Upon receipt of such notification, the division shall forward the information to the appropriate board which shall make a determination regarding the issuance of licensure. The applicant shall bear the cost for the criminal history record background check, including all costs of administering and processing the check, unless otherwise provided for by an individual enabling act. The Division of State Police shall promptly notify the division in the event an applicant or licensee, who was the subject of a criminal history record background check pursuant to this section, is convicted of a crime or offense in this State after the date the background check was performed.

For purposes of this act:

''Completed application'' means the submission of all of the information designated on the checklist, adopted pursuant to section 1 of P.L.1991, c.421 (C.13:1D-101), for the class or category of permit for which application is made.

''Permit'' has the same meaning as defined in section 1 of P.L.1991, c. 421 (C.13:1D-101).

45:1-21.1. Annual summary of compliance information and attendance at continuing education seminars; costs; information deemed public records

a. A board obtaining information from the Department of Environmental Protection pursuant to section 1 of P.L.1991, c. 418 (C. 13:1D-110) on the compliance of a member of a regulated profession with the requirements for completed applications of the department, shall annually develop a detailed written summary of the information gathered by the department pursuant to P.L.1991, c. 418 (C. 13:1D-110) regarding compliance with the department's requirements for completed applications and attendance records for continuing education seminars required to be filed with the department pursuant to section 2 of P.L.1991, c. 419 (C. 13:1D-117).

b. Any reasonable costs incurred in preparation of the report required pursuant to this section may be included in the charges authorized pursuant to P.L.1974, c. 46 (C. 45:1-3.2).

c. Information required to be compiled by a board pursuant to this section, shall be deemed to be public records subject to the requirements of P.L.1963, c. 73 (C. 47:1A-1 et seq.).

45:1-21.2. Suspension of certain licenses; hearing

The director or a board shall suspend, as appropriate, after a hearing, the license, registration or certification of any person who has been certified by a lender or guarantor and reported to the director or the board, as the case may be, for nonpayment or default of a State or federal direct or guaranteed educational loan. The license, registration or certification shall not be reissued until the person provides the director or board with a written release issued by the lender or guarantor stating that the

person has cured the default or is making payments on the loan in accordance with a repayment agreement approved by the lender or guarantor. If the person has continued to meet all other requirements for licensure, registration or certification during the suspension, reinstatement shall be automatic upon receipt of the notice and payment of any reinstatement fee the director or the board may impose.

45:1-21.3. Licensed health care professionals; penalties for violation of § 30:6D-5.3

A health care professional licensed or otherwise authorized to practice as a health care professional pursuant to Title 45 of the Revised Statutes who violates the provisions of section 3 of P.L.2003, c. 191 (C.30: 6D-5.3) shall, in addition to being liable to a civil penalty pursuant to section 4 of P.L.2003, c. 191 (C.30:6D-5.4), be subject to revocation of that individual's professional license or other authorization to practice as a health care professional by the appropriate licensing board in the Division of Consumer Affairs in the Department of Law and Public Safety, after appropriate notice and opportunity for a hearing.

45:1-22. Additional or alternative penalties to revocation, suspension or refusal to renew; temporary order suspending or limiting license; subpoena

In addition or as an alternative, as the case may be, to revoking, suspending or refusing to renew any license, registration or certificate issued by it, a board may, after affording an opportunity to be heard:

a. Issue a letter of warning, reprimand, or censure with regard to any act, conduct or practice which in the judgment of the board upon consideration of all relevant facts and circumstances does not warrant the initiation of formal action;

b. Assess civil penalties in accordance with this act;

c. Order that any person violating any provision of an act or regulation administered by such board to cease and desist from future violations thereof or to take such affirmative corrective action as may be necessary with regard to any act or practice found unlawful by the board;

d. Order any person found to have violated any provision of an act or regulation administered by such board to restore to any person aggrieved by an unlawful act or practice, any moneys or property, real or personal, acquired by means of such act or practice; provided, however, no board shall order restoration in a dollar amount greater than those moneys received by a licensee or his agent or any other person violating the act or regulation administered by the board;

e. Order any person, as a condition for continued, reinstated or renewed licensure, to secure medical or such other professional treatment as may be necessary to properly discharge licensee functions;

f. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to any medical or diagnostic testing and monitoring or psychological evaluation which may be required to evaluate whether continued practice may jeopardize the safety and welfare of the public;

g. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to take and successfully complete educational training determined by the board to be necessary;

h. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to submit to any supervision, monitoring or limitation on practice determined by the board to be necessary.

A board may, upon a duly verified application of the Attorney General that either provides proof of a conviction of a court of competent jurisdiction for a crime or offense involving moral turpitude or relating adversely to the regulated profession or occupation, or alleges an act or practice violating any provision of an act or regulation administered by such board, enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint; provided, however, no such temporary order shall be entered unless the application made to the board palpably demonstrates a clear and imminent danger to the public health, safety and welfare and notice of such application is given to the licensee affected by such order. If, upon review of the Attorney General's application, the board determines that, although no palpable demonstration of a clear and imminent danger has been made, the licensee's continued unrestricted practice pending plenary hearing may pose a risk to the public health, safety and welfare, the board may order the licensee to submit to medical or diagnostic testing and monitoring, or psychological evaluation, or an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety. In any administrative proceeding commenced on a complaint alleging a violation of an act or regulation administered by a board, such board may issue subpoenas to compel the attendance of witnesses or the production of books, records, or documents at the hearing on the complaint.

45:1-23. Summary proceeding in Superior Court; injunction; orders necessary to prevent unlawful practice or remedy past unlawful activity

Whenever it shall appear to a board, the director or the Attorney General that a violation of any act, including the unlicensed practice of the regulated profession or occupation, or regulation administered by such board has occurred, is occurring, or will occur, the Attorney General, in addition to any other proceeding authorized by law, may seek and obtain in a summary proceeding in the Superior Court an injunction prohibiting such act or practice. In any such proceeding the court may assess a civil penalty in accordance with the provisions of this act, order restoration to any person in interest of any moneys or property, real or personal, acquired by means of an unlawful act or practice and may enter such orders as may be necessary to prevent the performance of an unlawful practice in the future and to fully remedy any past unlawful activity. In any action brought pursuant to this section, the court shall not suspend or revoke any license issued by a board.

45:1-24. Failure to comply with order of board directing payment of penalties or restoration of moneys or property; enforcement

Upon the failure of any person to comply within 10 days after service of any order of a board directing payment of penalties or restoration of moneys or property, the Attorney General or the secretary of such board may issue a certificate to the Clerk of the Superior Court that such person is indebted to the State for the payment of such penalty and the moneys or property ordered restored. A copy of such certificate shall be served upon the person against whom the order was entered. Thereupon the clerk shall immediately enter upon his record of docketed judgments the name of the person so indebted and of the State, a designation of the statute under which the penalty is imposed, the amount of the penalty imposed, and amount of moneys ordered restored, a listing of property ordered restored, and the date of the certification. Such entry shall have the same force and effect as the entry of a docketed judgment in the Superior Court, and the Attorney General shall have all rights and remedies

of a judgment creditor in addition to exercising any other available remedies. Such entry, however, shall be without prejudice to the right of appeal to the Appellate Division of the Superior Court from the board's order.

An action to enforce the provisions of any order entered by a board or to collect any penalty levied thereby may be brought in any municipal court or the Superior Court in summary manner pursuant to the Penalty Enforcement Act, (N.J.S. 2A:58-1 et seq.) and the rules of court governing the collection of civil penalties. Process in such action shall be by summons or warrant, and in the event that the defendant fails to answer such action, the court shall issue a warrant for the defendant's arrest for the purpose of bringing such person before the court to satisfy any order entered.

45:1-25. Violations; civil penalty; action to collect or enforce

a. Any person who engages in any conduct in violation of any provision of an act or regulation administered by a board shall, in addition to any other sanctions provided herein, be liable to a civil penalty of not more than $10,000 for the first violation and not more than $20,000 for the second and each subsequent violation. For the purpose of construing this section, each act in violation of any provision of an act or regulation administered by a board shall constitute a separate violation and shall be deemed a second or subsequent violation under the following circumstances:

(1) an administrative or court order has been entered in a prior, separate and independent proceeding;

(2) the person is found within a single proceeding to have committed more than one violation of any provision of an act or regulation administered by a board; or

(3) the person is found within a single proceeding to have committed separate violations of any provision of more than one act or regulation administered by a board.

b. In lieu of an administrative proceeding or an action in the Superior Court, the Attorney General may bring an action in the name of any board for the collection or enforcement of civil penalties for the violation of any provision of an act or regulation administered by such board. Such action may be brought in summary manner pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c. 274 (C.2A:58-10 et seq.) and the rules of court governing actions for the collection of civil penalties in the municipal court where the offense occurred. Process in such action may be by summons or warrant and in the event that the defendant in such action fails to answer such action, the court shall, upon finding an unlawful act or practice to have been committed by the defendant, issue a warrant for the defendant's arrest in order to bring such person before the court to satisfy the civil penalties imposed. In any action commenced pursuant to this section, the court may order restored to any person in interest any moneys or property acquired by means of an unlawful act or practice.

c. Any action alleging the unlicensed practice of a profession or occupation shall be brought pursuant to this section or, where injunctive relief is sought, by an action commenced in the Superior Court.

d. In any action brought pursuant to this act, a board or the court may order the payment of costs for the use of the State, including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs.

45:1-26. Repeal of inconsistent acts and parts of acts

All acts and parts of acts inconsistent with this act are hereby superseded and repealed.

45:1-27. Severability

If any provision of this law or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the law which can be given effect without the invalid provision or application, and to this end the provisions of this law are severable.

CHAPTER 21.

DANGEROUS SUBSTANCES CONTROL LAW

24:21-1. Short title

This act shall be known and may be cited as the ‘‘New Jersey Controlled Dangerous Substances Act.’’

24:21-2. Definitions

As used in this act:

‘‘Administer’’ means the direct application of a controlled dangerous substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by: (1) a practitioner (or, in his presence, by his lawfully authorized agent), or (2) the patient or research subject at the lawful direction and in the presence of the practitioner.

‘‘Agent’’ means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser but does not include a common or contract carrier, public warehouseman, or employee thereof. ‘‘Bureau of Narcotics and Dangerous Drugs’’ means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice.

‘‘Commissioner’’ means the State Commissioner of Health.

‘‘Controlled dangerous substance’’ means a drug, substance, or immediate precursor in Schedules I through V of article 2 of this act.[1] The term shall not include distilled spirits, wine, malt beverages, as those terms are defined or used in R.S. 33:1-1 et seq., or tobacco and tobacco products.

‘‘Counterfeit substance’’ means a controlled dangerous substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

‘‘Deliver’’ or ‘‘delivery’’ means the actual, constructive, or attempted transfer from one person to nother of a controlled dangerous substance, whether or not there is an agency relationship.

‘‘Dispense’’ means to deliver a controlled dangerous substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

‘‘Dispenser’’ means a practitioner who dispenses.

‘‘Distribute’’ means to deliver other than by administering or dispensing a controlled dangerous substance.

‘‘Distributor’’ means a person who distributes.

‘‘Drugs’’ means (a) substances recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) substances (other than food) intended to affect

the structure or any function of the body of man or other animals; and (d) substances intended for use as a component of any article specified in subsections (a), (b) and (c) of this section; but does not include devices or their components, parts or accessories.

''Drug dependent person'' means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from the use of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses, including but not limited to a strong compulsion to take the substance on a recurring basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

''Hashish'' means the resin extracted from any part of the plant GenusCannabis. and any compound, manufacture, salt, derivative, mixture, or preparation of such resin.

''Marihuana'' means all parts of the plant Genus Cannabis L., whether growing or not; the seeds thereof; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds, except thosecontaining resin extracted from such plant; but shall not include the maturestalks of such plant, fiber produced from such stalks, oil or cake made fromthe seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

''Manufacture'' means the production, preparation, propagation, compounding, conversion or processing of a controlled dangerous substance, either directly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled dangerous substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled dangerous substance:

(1) by a practitioner as an incident to his administering or dispensing of a controlled dangerous substance in the course of his professional practice, or

(2) by a practitioner (or under his supervision) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

''Narcotic drug'' means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) Opium, coca leaves, and opiates;

(b) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates;

(c) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in subsections (a) and (b), except that the words ''narcotic drug'' as used in this act shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

''Official written order'' means an order written on a form provided for that purpose by the Attorney General of the United States or his delegate, under any laws of the United States making provisions therefor, if such order forms are authorized and required by the federal law, and if no such form is provided, then on an official form provided for that purpose by the State Department of Health.

''Opiate'' means any dangerous substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under

section 3 of this act,[2] the dextrorotatory isomer of 3-methoxy-n- methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

''Opium poppy'' means the plant of the species Papaver somniferum L., except the seeds thereof.

''Person'' means any corporation, association, partnership, trust, other institution or entity or one or more individuals.

''Pharmacist'' means a registered pharmacist of this State.

''Pharmacy owner'' means the owner of a store or other place of business where controlled dangerous substances are compounded or dispensed by a registered pharmacist; but nothing in this chapter contained shall be construed as conferring on a person who is not registered or licensed as a pharmacist any authority, right or privilege that is not granted to him by the pharmacy laws of this State.

''Poppy straw'' means all parts, except the seeds, of the opium poppy, after\mowing.

''Practitioner'' means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this State.

(a) ''Physician'' means a physician authorized by law to practice medicine in this or any other state and any other person authorized by law to treat sick and injured human beings in this or any other state and

(b) ''Veterinarian'' means a veterinarian authorized by law to practice veterinary medicine in this State.

(c) ''Dentist'' means a dentist authorized by law to practice dentistry in this State.

(d) ''Hospital'' means any federal institution, or any institution for the careand treatment of the sick and injured, operated or approved by the appropriate State department as proper to be entrusted with the custody and professional use of controlled dangerous substances.

(e) ''Laboratory'' means a laboratory to be entrusted with the custody of narcotic drugs and the use of controlled dangerous substances for scientific, experimental and medical purposes and for purposes of instruction approved by the State Department of Health.

''Production'' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled dangerous substance.

''Immediate precursor'' means a substance which the State Department of Health has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled dangerous substance, the control of which is necessary to prevent, curtail, or limit such manufacture.

''State'' means the State of New Jersey.

''Ultimate user'' means a person who lawfully possesses a controlled dangerous substance for his own use or for the use of a member of his household or for administration to an animal owned by him or by a member of his household.

[1] N.J.S.A. §§ 24:21-5 et seq.

[2] N.J.S.A. § 24:21-3.

24:21-3. Authority to control

a. The commissioner shall administer the provisions of this act and may add substances to or delete or reschedule all substances enumerated in the schedules in sections 5 through 8 of this act.[1] In determining whether to control a substance, the commissioner shall consider the following:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) State of current scientific knowledge regarding the substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this article.

After considering the above factors, the commissioner shall make findings with respect thereto and shall issue an order controlling the substance if he finds that the substance has a potential for abuse.

b. If the commissioner designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

c. If any substance is designated, rescheduled or deleted as a controlled dangerous substance under Federal law and notice thereof is given to the commissioner, the commissioner shall similarly control the substance under this act after the expiration of 30 days from publication in the Federal Register of a final order designating a substance as a controlled dangerous substance or rescheduling or deleting a substance, unless within that 30-day period, the commissioner objects to inclusion, rescheduling, or deletion. In that case, the commissioner shall cause to be published in the New Jersey Register and made public the reasons for his objection and shall afford all interested parties an opportunity to be heard. At the conclusion of any such hearing, the commissioner shall publish and make public his decision, which shall be final unless the substance is specifically otherwise dealt with by an act of the Legislature. Upon publication of objection to inclusion or rescheduling under this act by the commissioner, control of such substance under this section shall automatically be stayed until such time as the commissioner makes public his final decision.

The Commissioner of Health may by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the provisions of Federal or State law, be lawfully sold over the counter without a prescription, unless otherwise controlled pursuant to rules and regulations promulgated by the department.

d. The State Department of Health shall update and republish the schedules in sections 5 through 8 on a semiannual basis for 2 years from the effective date of this act and thereafter on an annual basis.

[1]N.J.S.A. §§ 24:21-5 to 24:21-8.

24:21-4. Schedules of controlled substances

The schedules contained in sections 5 through 8 of this actπ include the controlled dangerous substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated.

[1]N.J.S.A. §§ 24:21-5 to 24:21-8.

24:21-5. Schedule I

a. Tests. The commissioner shall place a substance in Schedule I if he finds that the substance: (1) has high potential for abuse; and (2) has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision.

b. The controlled dangerous substances listed in this section are included in Schedule I, subject to any revision and republishing by the commissioner pursuant to section 3d,[1] and except to the extent provided in any other schedule.

c. Any of the following opiates, including their isomers, esters, and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) Acetylmethadol
(2) Allylprodine
(3) Alphacetylmethadol
(4) Alphameprodine
(5) Alphamethadol
(6) Benzethidine
(7) Betacetylmethadol
(8) Betameprodine
(9) Betamethadol
(10) Betaprodine
(11) Clonitazene
(12) Dextromoramide
(13) Dextrorphan
(14) Diampromide
(15) Diethylthiambutene
(16) Dimenoxadol
(17) Dimepheptanol
(18) Dimethylthiambutene
(19) Dioxaphetyl butyrate
(20) Dipipanone
(21) Ethylmethylthiambutene
(22) Etonitazene
(23) Etoxeridine

(24) Furethidine
(25) Hydroxypethidine
(26) Ketobemidone
(27) Levomoramide
(28) Levophenacylmorphan
(29) Morpheridine
(30) Noracymethadol
(31) Norlevorphanol
(32) Normethadone
(33) Norpipanone
(34) Phenadoxone
(35) Phenampromide
(36) Phenomorphan
(37) Phenoperidine
(38) Piritramide
(39) Proheptazine
(40) Properidine
(41) Racemoramide
(42) Trimeperidine.

d. Any of the following narcotic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine
(2) Acetylcodone
(3) Acetyldihydrocodeine
(4) Benzylmorphine
(5) Codeine methylbromide
(6) Codeine-N-Oxide
(7) Cyprenorphine
(8) Desomorphine
(9) Dihydromorphine
(10) Etorphine
(11) Heroin
(12) Hydromorphinol
(13) Methyldesorphine
(14) Methylhydromorphine
(15) Morphine methylbromide
(16) Morphine methylsulfonate

(17) Morphine-N-Oxide

(18) Myrophine

(19) Nicocodeine

(20) Nicomorphine

(21) Normorphine

(22) Phoclodine

(23) Thebacon.

e. Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine

(2) 5-methoxy-3,4-methylenedioxy amphetamine

(3) 3,4,5-trimethoxy amphetamine

(4) Bufotenine

(5) Diethyltryptamine

(6) Dimethyltryptamine

(7) 4-methyl-2,5-dimethoxylamphetamine

(8) Ibogaine

(9) Lysergic acid diethylamide

(10) Marihuana

(11) Mescaline

(12) Peyote

(13) N-ethyl-3-piperidyl benzilate

(14) N-methyl-3-piperidyl benzilate

(15) Psilocybin

(16) Psilocyn

(17) Tetrahydrocannabinols.

[1]N.J.S.A. § 24:21-3.

24:21-6. Schedule II

a. Tests. The commissioner shall place a substance in Schedule II if he finds that the substance: (1) has high potential abuse; (2) has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and (3) abuse may lead to severe psychic or physical dependence.

b. The controlled dangerous substances listed in this section are included in Schedule II, subject to any revision and republishing by the commissioner pursuant to section 3d,[1] and except to the extent provided in any other schedule.

c. Any of the following substances except those narcotic drugs listed in other schedules whether produced directly or indirectly by extraction from substances of vegetable origin, or inde pendently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause 1, except that these substances shall not include the isoquinaline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extractions which do not contain cocaine or ecogine.[2]

d. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine

(2) Anileridine

(3) Bezitramide

(4) Dihydrocodeine

(5) Diphenoxylate

(6) Fentanyl

(7) Isomethadone

(8) Levomethorphan

(9) Levorphanol

(10) Metazocine

(11) Methadone

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid

(14) Pethidine

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid

(18) Phenazocine

(19) Piminodine

(20) Racemethorphan

(21) Racemorphan.

[1]N.J.S.A. § 24:21-3.

[2]So in enrolled bill.

24:21-7. Schedule III

a. Tests. The commissioner shall place a substance in Schedule III if he finds that the substance: (1) has a potential for abuse less than the substances listed in Schedules I and II; 1 (2) has currently accepted medical use in treatment in the United States; and (3) abuse may lead to moderate or low physical dependence or high psychological dependence.

b. The controlled dangerous substances listed in this section are included in Schedule III, subject to any revision and republishing by the commissioner pursuant to section 3d.,2 and except to the extent provided in any other schedule.

c. Any material, compound, mixture, or preparation which contains any quantity of the following substances associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

d. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules

(2) Chlorhexadol

(3) Glutethimide

(4) Lysergic acid

(5) Lysergic acid amide

(6) Methyprylon

(7) Phencyclidine

(8) Sulfondiethylmethane

(9) Sulfonethylmethane

(10) Sulfonmethane

(11) Ketamine hydrochloride.

e. Nalorphine.

f. Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.80 grams of codeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.80 grams of codeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized the rapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.80 grams of dihydrocodeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium or any of its salts per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine or any of its salts per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

g. The commissioner may by regulation except any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections a. and b. of this schedule from the application of all or any part of this act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system; provided, that such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.[π]

[1]N.J.S.A. §§ 24:21-5, 24:21-6.
[2]N.J.S.A. § 24:21-3.

24:21-8. Schedule IV

a. Tests. The commissioner shall place a substance in Schedule IV if he finds that the substance: (1) has low potential for abuse relative to the substances listed in Schedule III;1 (2) has currently accepted medical use in treatment in the United States; and (3) may lead to limited physical dependence or psychological dependence relative to the substances listed in Schedule III.

b. The controlled dangerous substances listed in this section are included in Schedule IV.

c. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Barbital

(2) Chloral betaine

(3) Chloral hydrate

(4) Ethchlorovynol

(5) Ethinamate

(6) Methohexital

(7) Meprobamate

(8) Methylphenobarbital

(9) Paraldehyde

(10) Petrichloral

(11) Phenobarbital

d. The commissioner may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection c. from the application of all or any part of this act if the compound, mixture or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

[1]N.J.S.A. § 24:21-7.

24:21-8.1. Schedule V

a. Tests. The commissioner shall place a substance in Schedule V if he finds that the substance: (1) has low potential for abuse relative to the substances listed in Schedule IV; [1] (2) has currently accepted medical use in treatment in the United States; and (3) has limited physical dependence or psychological dependence liability elative to the substances listed in Schedule IV.

b. The controlled dangerous substances listed in this section are included in Schedule V.

c. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine or any of its salts per 100 milliliters or per 100 grams;

(3) Not more than 50 milligrams of ethylmorphine or any of its salts per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium or any of its salts per 100 milliliters or per 100 grams.

[1]N.J.S.A. § 24:21-8.

24:21-8.2. Repealed by L.1992, c. 71, § 3, eff. July 30, 1992

24:21-9. Rules and regulations

The commissioner is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled dangerous substances within this State.

24:21-10. Registration requirements

a. Every person who manufactures, distributes, or dispenses any controlled dangerous substance within this State or who proposes to engage in the manufacture, distribution, or dispensing of any controlled dangerous substance within this State, shall obtain annually a registration issued by the State Department of Health in accordance with rules and regulations promulgated by it.

b. Persons registered by the commissioner under this act to manufacture, distribute, dispense, or conduct research with controlled dangerous substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this article.

c. The following persons shall not be required to register and may lawfully have under their control or possess controlled dangerous substances under the provisions of this act; provided, however, that nothing in this section shall be construed as conferring on a person who is not registered or licensed as a practitioner or as a pharmacist any authority, right or privilege that is not granted him by the laws of this State:

(1) An agent, or an employee thereof, of any registered manufacturer, distributor, or dispenser of any controlled dangerous substance if such agent is acting in the usual course of his business or employment;

(2) A common carrier or warehouseman, or an employee thereof, whose possession of any controlled dangerous substance is in the usual course of his business or employment;

(3) An ultimate user or a person in possession of any controlled dangerous substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance;[1]

(4) Peace officers or employees in the performance of their official duties requiring possession or control of controlled dangerous substances; or to temporary incidental possession by employees or agents of persons lawfully entitled to possession, or by persons whose possession is authorized for the purpose of aiding peace officers in performing their official duties.

d. The commissioner may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

e. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled dangerous substances.

f. The commissioner is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

[1]N.J.S.A. § 24:21-8.1.

24:21-11. Registration

a. The State Department of Health shall not register an applicant to manufacture or distribute controlled dangerous substances included in Schedules I through IV of article 2 of this act [1] unless it determines that the issuance of such registration is consistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled dangerous substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable State and local laws;

(3) Any convictions of the applicant under any Federal and State laws relating to any controlled dangerous substance;

(4) Past experience in the manufacture of controlled dangerous substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant false or fraudulent material in any application filed under this act;

(6) Suspension or revocation of the applicant's Federal registration to manufacture, distribute, or dispense controlled dangerous substances as authorized by Federal law; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

b. Registration granted under subsection a. of this section shall not entitle a registrant to manufacture and distribute controlled dangerous substances in Schedule I or II other than those specified in the registration.

c. Practitioners shall be registered to dispense substances in Schedules II through IV if they are authorized to dispense or conduct research under the law of this State. The commissioner need not require separate registration under this article for practitioners engaging in research with nonnarcotic controlled dangerous substances in Schedules II through IV where the registrant is already registered under this article in another capacity. Practitioners registered under Federal law to conduct research in Schedule I substances are permitted to conduct research in Schedule I substances within this State upon furnishing the commissioner evidence of that Federal registration.

d. Compliance by manufacturers and distributors with the provisions of the Federal law respecting registration (excluding fees) entitles them to be registered under this act.

e. The State Department of Health shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution or dispensing of any controlled dangerous substances prior to the effective date of this act and who are registered or licensed by the State.

f. An incorporated humane society or a licensed animal control facility may designate an officer, a member of its board of trustees, the owner, the operator or the manager as its duly authorized agent. The State Department of Health shall, consistent with the public interest, register such duly authorized agent for the limited purpose of buying, possessing, and dispensing to registered and certified personnel sodium pentobarbital to euthanize injured, sick, homeless and unwanted domestic pets or domestic or wild animals. The duly authorized agent shall file, on a quarterly basis, a report of any purchase, possession and use of sodium pentobarbital, which report shall be certified by the humane society or animal control facility as to its accuracy and validity. This report shall be in addition to any other recordkeeping and reporting requirements of State and Federal law and regulation.

The State Department of Health shall adopt rules and regulations providing for the registration and certification of any individual who, under the direction of the duly authorized and registered agent of an incorporated humane society or licensed animal control facility, uses sodium pentobarbital to euthanize injured, sick, homeless and unwanted domestic pets or domestic or wild animals. The State Department of Health may also adopt such other rules and regulations as shall provide for the safe and efficient use of sodium pentobarbital by animal control facilities and humane societies. Nothing herein

shall be deemed to waive any other requirement imposed on animal control facilities and humane societies by State and Federal law and regulation.

[1]N.J.S.A. §§ 24:21-5 to 24:21-8.

24:21-12. Denial, revocation, or suspension of registration

a. A registration pursuant to section 11 1 to manufacture, distribute, or dispense a controlled dangerous substance, may be suspended or revoked by the commissioner upon a finding that the registrant:

(1) Has materially falsified any application filed pursuant to this act or required by this act; or

(2) Has been convicted of an indictable offense under this act or any law of the United States, or of any State, relating to any substance defined herein as a controlled dangerous substance; or

(3) Has violated or failed to comply with any duly promulgated regulation of the commissioner and such violation or failure to comply reflects adversely on the licensee's reliability and integrity with respect to controlled dangerous substances; or

(4) Has had his Federal registration suspended or revoked by competent Federal authority and is no longer authorized by Federal law to engage in the manufacturing, distribution, or dispensing of controlled dangerous substances; or

(5) Has had his registration suspended or revoked by competent authority of another state for violation of its laws or regulations comparable to those of this State relating to the manufacture, distribution or dispensing of controlled dangerous substances.

b. The commissioner may limit revocation or suspension of a registration to the particular controlled dangerous substance with respect to which grounds for revocation or suspension exist.

c. Before taking action pursuant to this section or pursuant to a denial of registration under section 11, the commissioner shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the commissioner at a time and place stated in the order, but in no event less than 30 days after the date of receipt of the order unless an earlier date is requested by the applicant or registrant and agreed to by the commissioner. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with the provisions of the ''Administrative Procedure Act'' (C. 52:14B-1 et seq.). Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this act or any law of the State.

d. The commissioner may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section in cases where he finds that there is an imminent danger to the public health or safety. Such suspensions shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the commissioner or dissolved by a court of competent jurisdiction.

e. In the event the commissioner suspends or revokes a registration granted under section 11, all controlled dangerous substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may in the discretion of the commissioner be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable

substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled dangerous substances may be forfeited to the State.

f. The commissioner shall promptly notify the Bureau of Narcotics and Dangerous Drugs of all orders suspending or revoking registration and all forfeitures of controlled dangerous substances.

[1]N.J.S.A. § 24:21-11.

24:21-13. Records of registrants

Persons registered to manufacture, distribute, or dispense controlled dangerous substances under this act shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of Federal law and with such additional rules as may be issued by the commissioner.

24:21-14. Order forms

a. Controlled dangerous substances in Schedule I and IIπ shall be distributed only by a registrant, pursuant to an official written order form, clearly identifying it as covering or relating to Schedule I and Schedule II, or either thereof, controlled dangerous substances and bearing the registration number of the registrant. Except as provided herein, compliance with Federal law respecting order forms shall be deemed compliance with this section.

b. A pharmacist, only upon an official written order, may sell to a practitioner in quantities not exceeding one ounce at any one time, aqueous or oleaginous solutions compounded by him of which the content of narcotic drugs or other controlled dangerous substances does not exceed a proportion greater than 20% of the complete solution, to be used for medical purposes.

c. An official written order for any controlled dangerous substance in Schedule I or Schedule II shall be signed in triplicate by the person giving said order or by his duly authorized agent. The original and triplicate shall be presented to the person who sells or dispenses the controlled dangerous substance or substances named therein. In the event of the acceptance of such order by said person, except as may be otherwise required by rule, regulation, or order of the commissioner, each party to the transaction shall preserve his copy of such order for a period of 2 years, in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

[1]N.J.S.A. §§ 24:21-5, 24:21-6.

24:21-15. Prescriptions

a. Except when dispensed directly in good faith by a practitioner, other than a pharmacist, in the course of his professional practice only, to an ultimate user, no controlled dangerous substance included in Schedule II,[1] which is a prescription drug as defined in R.S. 45:14-14 may be dispensed without the written prescription of a practitioner; provided that in emergency situations, as prescribed by the State Department of Health by regulation, such drug may be dispensed upon oral prescription reduced promptly to writing and filed by the pharmacist, if such oral prescription is authorized by Federal law. Prescriptions shall be retained in conformity with the requirements of section 13 of this act.[2] No prescription for a Schedule II substance may be refilled.

b. Except when dispensed directly in good faith by a practitioner, other than a pharmacist, in the course of his professional practice only, to an ultimate user, no controlled angerous substance included in Schedule III and IV [3] which is a prescription drug as defined in R.S. 45:14-14 may be dispensed without a written or oral prescription. Such prescription may not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times after the date of the prescription, unless renewed by the practitioner.

c. No controlled dangerous substance included in Schedule V [4] may be distributed or dispensed other than for a valid and accepted medical purpose.

d. A practitioner other than a veterinarian who prescribes a controlled dangerous substance in good faith and in the course of his professional practice may administer the same or cause the same to be administered by a nurse or intern under his direction and supervision.

e. A veterinarian who prescribes a controlled dangerous substance not for use by a human being in good faith and in the course of his professional practice may administer the same or cause the same to be administered by an assistant or orderly under his direction and supervision.

f. A person who has obtained a controlled dangerous substance from the prescribing practitioner for administration to a patient during the absence of the practitioner shall return to the practitioner any unused portion of the substance when it is no longer required by the patient or when its return is requested by the practitioner.

g. Whenever it appears to the State Department of Health that a drug not considered to be a prescription drug under existing State law should be so considered because of its abuse potential, it shall so advise the State Board of Pharmacy and furnish to it all available data relevant thereto.

[1]N.J.S.A. § 24:21-6.
[2]N.J.S.A. § 24:21-13.
[3]N.J.S.A. § 24:21-7, 24:21-8.
[4]N.J.S.A. § 24:21-8.1.

24:21-16. Form of label on containers of manufacturers and wholesalers; altering or removing label

Whenever a manufacturer sells or dispenses a controlled dangerous substance in a package prepared by him, he shall securely affix to each package in which that substance is contained a label showing in legible English the name and address of the vendor and the quantity, kind and form of the substance contained therein. Whenever a wholesaler sells or dispenses a controlled dangerous substance in any package or shipping container other than the package in which received from the manufacturer, he shall securely affix to such package a label showing in legible English his name and address. No person except a pharmacist for the purpose of filling a prescription under this act, shall alter, deface or remove any label so affixed by the manufacturer.

24:21-17. Form of label to be used by pharmacists; altering or removing label

Whenever a pharmacist sells or dispenses any controlled dangerous substance on a prescription issued by a practitioner, he shall affix to the container in which such drug is sold or dispensed, a label showing his own name, address, and registry number, or the name, address, and registry number of the pharmacist or pharmacy owner for whom he is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the

practitioner by whom the prescription was issued; the brand name or generic name of the drug dispensed unless the prescriber states otherwise on the prescription, such directions as may be stated on the prescription and such directions as may be required by rules or regulations promulgated by the commissioner.

No person shall alter, deface, or remove any label so affixed as long as any of the original contents remain.

24:21-18. Repealed by L.1999, c. 90, ß 19, eff. May 3, 1999

24:21-19 to 24:21-20. Repealed by L.1987, c. 106, § 25, operative July 9, 1987

24:21-21. Prohibited acts C.-Records and order forms of registered manufacturers and distributors-Penalties

a. It shall be unlawful for any person:

(1) Who is subject to the requirements of article 3 of this act to distribute or dispense a controlled dangerous substance in violation of section 14; [1]

(2) Who is a registrant, to manufacture, distribute, or dispense a controlled dangerous substance not authorized by his registration;

(3) To omit, remove, alter, or obliterate a symbol, label or mark required by Federal or State law;

(4) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this act;

(5) To refuse, any entry into any premises or inspection authorized by this act; or,

(6) Knowingly to keep or maintain any store, shop, warehouse, dwelling house, building, vehicle, boat, aircraft, or any place whatever, which is resorted to by persons using controlled dangerous substances in violation of this act for the purpose of using such substances, or which is used for the keeping or selling of the same in violation of this act.

b. Any person who violates this section shall be subject to a fine of not more than $25,000.00; provided, that if the violation is prosecuted by an accusation or indictment which alleges that the violation was committed knowingly or intentionally, and the trier of fact specifically finds that the violation was committed knowingly or intentionally, such person is guilty of a high misdemeanor and shall be punished by imprisonment for not more than 3 years, or by a fine of not more than $25,000.00, or both.

[1]N.J.S.A. § 24:21-14.

24:21-22. Prohibited acts D.-Fraud or misrepresentation by registered manufacturers or distributors-Penalties

a. It shall be unlawful for any person knowingly or intentionally:

(1) Who is a registrant to distribute a controlled dangerous substance classified in Schedule I or II,[1] in the course of his legitimate business, except pursuant to an order form as required by section 14 of this act; [2]

(2) To use in the course of the manufacture or distribution of a controlled dangerous substance a registration number which is fictitious, revoked, suspended or issued to another person;

(3) (Deleted by amendment, P.L.1987, c. 106).

(4) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act; or

(5) To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit controlled dangerous substance.

b. Any person who violates this section shall be punished by imprisonment for not more than three years, or by a fine of not more than $30,000.00, or both.

[1]N.J.S.A. §§ 24:21-5, 24:21-6.

[2]N.J.S.A. § 24:21-14.

24:21-23. General penalty

Any person who violates any provision of this act for which no specific penalty is provided shall be guilty of a disorderly persons offense.

24:21-24. Attempt, endeavor and conspiracy

a. Any person who attempts, endeavors or conspires to commit any offense defined in this act is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the endeavor or conspiracy.

b. (Deleted by amendment, P.L.1987, c. 106.)

24:21-25. Additional penalties

Any penalty imposed for violation of this act shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law. In any case where a violation of this act is violation of a Federal law or the law of another state, the conviction or acquittal under Federal law or the law of another state for the same act is a bar to prosecution in this State.

24:21-26, 24:21-27. Repealed by L.1987, c. 106, § 25, operative July 9, 1987

24:21-28. Repealed by L.1979, c. 178, § 147, eff. Sept. 1, 1979

24:21-29. Second or subsequent offenses

a. Any person convicted of any offense under this act, if the offense is a second or subsequent offense, shall be punished by a term of imprisonment of up to twice that otherwise authorized, by up to twice the fine otherwise authorized, or by both.

b. For purposes of this section, an offense shall be considered a second or subsequent offense, if, prior to the commission of the offense, the offender has at any time been convicted of an offense or offenses under this act or under any law of the United States or of any state relating to narcotic drugs, marihuana, depressant, stimulant, or hallucinogenic drugs.

24:21-30. Repealed by L.1987, c. 106, § 25, operative July 9, 1987

24:21-31. Powers of enforcement personnel

a. It is hereby made the duty of the State Department of Health, its officers, agents, inspectors and representatives, and of all peace officers within the State, and of the Attorney General and all county prosecutors, to enforce all provisions of this act, except those specifically delegated, and to cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states, relating to narcotic drugs or controlled dangerous substances, and it shall be the duty of the Board of Pharmacy in the Division of Professional Boards in the Department of Law and Public Safety, its officers, agents, inspectors and representatives also to assist the State Department of Health, peace officers and county prosecutors in the enforcement of all provisions of this act relating to the handling of controlled dangerous substances by pharmacy owners and pharmacists.

b. Authority is hereby granted to the Commissioner of Health:

(1) To promulgate all necessary rules and regulations for the efficient enforcement of this act;

(2) To promulgate, insofar as applicable, regulations from time to time promulgated by the Attorney General of the United States;

(3) To promulgate an order relative to any controlled dangerous substance under this act when the delay occasioned by acting through promulgation of a regulation would constitute an imminent danger to the public health or safety.

(a) An order of the commissioner shall take effect immediately, but it shall expire 120 days after promulgation thereof. Rules and regulations pursuant to such order may be adopted and promulgated by the commissioner but they shall not take effect until he has given due notice of his intention to take such action and has held a public hearing.

(b) Any person who denies that a drug or pharmaceutical preparation is properly subject to an order by the commissioner which applies the provisions of this act to such drug or pharmaceutical preparation, may apply to the commissioner for a hearing which must be afforded, except where a drug or pharmaceutical preparation has been the subject of a prior hearing or determination by the commissioner, in which case a hearing shall be discretionary with the commissioner. In such case a decision must be rendered by the commissioner or his designee within 48 hours of the request for a hearing. If the petitioning party is aggrieved by the decision, he shall have the right to apply relief shall be in the Superior Court of New Jersey by way of summary proceedings.

c. In addition to the powers set forth in subsection a., of this section, any officer or employee of the State Department of Health designated by the commissioner may:

(1) Execute search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this State;

(2) Make seizures of property pursuant to the provisions of this act; and

(3) Perform such other law enforcement duties as may be designated by the commissioner with the approval of the Attorney General.

24:21-32. Administrative inspections and warrants

a. Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of a court having jurisdiction in the municipality where the inspection or seizure is to be conducted, may, upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this act or regulations thereunder,

and seizures of property appropriate to such inspections. For the purposes of this section, ''probable cause'' means a valid public interest in the effective enforcement of the act or regulations sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant;

(2) A warrant shall issue only upon an affidavit of an officer or employee duly designated and having knowledge of the facts alleged, sworn to before the judge and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the item or types of property to be seized, if any. The warrant shall be directed to a person authorized by section 3 [1] to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge to whom it shall be returned;

(3) A warrant issued pursuant to this section must be executed and returned within 10 days of its date. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person executing the warrant. The clerk of the court, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant; and

(4) The judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall cause them to be filed with the court which issued such warrant.

b. The commissioner is authorized to make administrative inspections of controlled premises in accordance with the following provisions:

(1) For the purposes of this article only, ''controlled premises'' means:

(a) Places where persons registered or exempted from registration requirements under this act are required to keep records, and

(b) Places including factories, warehouses, establishments, and conveyances where persons registered or exempted from registration requirements under this act are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled dangerous substance.

(2) When so authorized by an administrative inspection warrant issued pursuant to subsection a. (1) of this section an officer or employee designated by the commissioner upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, shall have the right to enter controlled premises for the purpose of conducting an administrative inspection.

(3) When so authorized by an administrative inspection warrant, an officer or employee designated by the commissioner shall have the right:

(a) To inspect and copy records required by this act to be kept;

(b) To inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in subsection b. (5) of this section, all other things therein including records, files, papers, processes, controls, and facilities bearing on violation of this act; and

(c) To inventory any stock of any controlled dangerous substance therein and obtain samples of any such substance.

(4) This section shall not be construed to prevent entries and administrative inspections (including seizures of property) without a warrant:

(a) With the consent of the owner, operator or agent in charge of the controlled premises;

(b) In situations presenting imminent danger to health or safety;

(c) In situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(d) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; and,

(e) In all other situations where a warrant is not constitutionally required.

(5) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to:

(a) Financial data;

(b) Sales data other than shipment data;

(c) Pricing data;

(d) Personnel data; or

(e) Research data.

[1]N.J.S.A. § 24:21-31.

24:21-33. Injunctions

The Superior Court shall have jurisdiction in accordance with the rules of court to enjoin violations of this act.

24:21-34. Cooperative arrangements

a. The commissioner may cooperate with Federal and other State agencies in discharging his responsibilities concerning traffic in dangerous substances and in suppressing the abuse of dangerous substances. To this end, he is authorized to:

(1) Except as otherwise provided by law, arrange for the exchange of information between government officials concerning the use and abuse of dangerous substances; provided, however, that in no case shall any officer having knowledge by virtue of his office of any such prescription, order or record divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing board or officer to which prosecution or proceeding the person to whom the records relate, is a party;

(2) Coordinate and cooperate in training programs on dangerous substances law enforcement at the local and State levels;

(3) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled dangerous substances may be extracted.

b. Results, information, and evidence received from the Bureau of Narcotics and Dangerous Drugs relating to the regulatory functions of this act, including results of inspections conducted by that agency, may be relied upon and acted upon by the commissioner in conformance with his regulatory functions under this act.

24:21-35. Nuisances

The maintenance of any building, conveyance or premises whatever which is resorted to by persons for the unlawful manufacture, distribution, dispensing, administration or use of controlled dangerous substances shall constitute the keeping of a common nuisance.

24:21-36. Reports of conviction of manufacturers and practitioners

Whenever a manufacturer or practitioner is convicted of violating any provision of this act or of a rule or regulation issued thereunder or of any offense defined in chapters 35 or 36 of Title 2C of the New Jersey Statutes, the court shall cause a copy of the judgment and sentence and opinion of the court, if any, to be sent to the State Department or professional board, as the case may be, by which the defendant was registered or licensed.

24:21-37. Burden of proof; liabilities; immunity

a. It shall not be necessary for the State to negate any exemption or exception set forth in this act in any complaint, information, indictment or other pleading or in any trial, hearing, or other proceeding under this act, and the burden of proof of any such exemption or exception shall be upon the person claiming its benefit.

b. In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this act, he shall be presumed not to be the holder of such registration or form, and the burden of proof shall be upon him to rebut such presumption.

c. No liability shall be imposed by virtue of this act upon any duly authorized State officer, engaged in the enforcement of this act, who shall be engaged in the enforcement of any law or municipal ordinance relating to controlled dangerous substances.

24:21-38. Judicial review

All final determinations, findings and conclusions of the commissioner under this act shall be final and conclusive decisions of the matters involved, subject to the provisions for judicial review provided by the Rules of Court.

24:21-39. Reports by practitioners of drug dependent persons

Every practitioner, within 24 hours after determining that a person is a drug dependent person by reason of the use of a controlled dangerous substance for purposes other than the treatment of sickness or injury prescribed and administered as authorized by law, shall report such determination verbally or by mail to the Commissioner of the State Department of Health. Such a report by a physician shall be confidential and shall not be admissible in any criminal proceeding. The commissioner, in his discretion, may also treat any other reports submitted under this section as confidential if he determines that it is in the best interest of the drug dependent person and the public health and welfare. A practitioner who fails to make a report required by this section is a disorderly person.

24:21-40. Pending proceedings

a. Prosecutions for any violation of law occurring prior to the effective date of this act shall not be affected or abated by the repealers contained in section 47 of this act.[1]

b. Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of this act shall not be affected or abated by the repealers contained in section 47 of this act.

c. All administrative proceedings pending before any enforcing authority on the effective date of this act shall be continued and brought to final determination in accord with laws and regulations in effect prior to the effective date of this act. Such drugs placed under control prior to the effective date of this act which are not listed within Schedules I through IV [2] shall automatically be controlled and listed in the appropriate schedule.

d. The provisions of this act shall be applicable to violations of law, seizures and forfeiture, injunctive proceedings, administrative proceedings and investigations which occur following its effective date.

[1] N.J.S.A. § 24:21-45.

[2] N.J.S.A. §§ 24:21-5 to 24:21-8.

24:21-41. Continuation of regulations

Any orders, rules and regulations which have been promulgated under any law affected by this act and which are in effect on the day preceding the effective date of this act shall continue in effect until modified, superseded or repealed by the State Department of Health.

24:21-42. Uniformity of interpretation

This act shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it.

24:21-43. Severability

If any clause, sentence, subdivision, paragraph, section or part of this act be adjudged to be unconstitutional or invalid, such judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, subdivision, paragraph, section or part thereof directly involved in the case in which said judgment shall have been rendered.

24:21-44. Study of penalties relating to use and possession of marihuana

Within 1 year after the date the Federal Commission on Marihuana and Drug Abuse submits its report to the President and the United States Congress, the Legislature shall conduct a comprehensive study and review of the penalties established in this act concerning offenses relating to the use and possession of marihuana.

24:21-45. Repealer

The following acts and parts of acts are repealed:

R.S. 24:18-1 to 24:18-7, 24:18-9 to 24:18-16, 24:18-18 to 24:18-28, 24:18-30 to 24:18-48 (constituting the remaining sections in chapter 18 of Title 24 of the Revised Statutes not previously repealed); P.L.1953, chapter 190 (C. 24:18-24.1, 24:18-24.2); P.L.1951, chapter 57 (C. 24:18-38.1 to 24:18-38.3); P.L.1966, chapter 314, sections 1-3 (C. 24:6C-1 to 24:6C-3); N.J.S. 2A:170-8.

24:21-46 to 24:21-50. Repealed by L.1987, c. 106, ß 25, operative July 9, 1987

24:21-51. Repealed by L.1999, c. 90, ß 19, eff. May 3, 1999

24:21-52. Seizure in violation of act

Drug paraphernalia seized in violation of this act shall be subject to the forfeiture provisions of Chapter 64 of the ‘‘New Jersey Code of Criminal Justice’’ (N.J.S. 2C:64-1 et seq.).

24:21-53. Severability

If any provisions of sections 2, 3, 4, 5, 6 and 7 [1] or the application thereof to any person or circumstance are held invalid, the invalidity shall not affect other provisions or applications of the sections which can be given effect without the invalid provision or application, and to this end the provisions of sections 2, 3, 4, 5, 6 and 7 are severable.

[1]N.J.S.A. §§ 24:21-47 to 24:21-52, §§ 24:21-47 to 24:21-50 have been repealed

CHAPTER 65

CONTROLLED DANGEROUS SUBSTANCES

SUBCHAPTER 1. GENERAL PROVISIONS; REGISTRATION

8:65-1.1 Registration fees

(a) Manufacturers of controlled dangerous substances shall pay an annual fee of $200.00 at the time of application for registration or for renewal of registration.

(b) Distributors of controlled dangerous substances shall pay an annual fee of $100.00 at the time of application for registration or for renewal of registration.

(c) Dispensers of controlled dangerous substances or practitioners registered to conduct research with controlled dangerous substances shall pay an annual fee of $20.00 at the time of application for registration or for renewal of registration.

(d) Incorporated humane societies or licensed animal control facilities registered to purchase and administer sodium pentobarbital for the purpose of animal euthanasia shall pay an annual fee of $20.00 for registration or renewal of registration as a Dispenser in the category of hospital/clinic.

(e) A separate fee shall be paid for each separate place of business or professional practice for which registration is required.

(f) The following persons shall be exempt from payment of a fee for registration or renewal of registration:

1. Any hospital, clinic, institution, or other facility operated by any department of the State of New Jersey;
2. Any other agency, excluding individual State employees, for which the State of New Jersey would be responsible for payment of the fee, provided that such exemption is approved by the Commissioner of the New Jersey Department of Health and Senior Services; and
3. Hospitals and other facilities operated by any department of the United States of America.

(g) Exemption from payment of a fee for registration or renewal of registration does not relieve the person of the requirement to obtain a registration or of any other requirements or duties prescribed by law.

8:65-1.1A Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

''Commissioner'' means the Commissioner of the New Jersey Department of Health and Senior Services.

''Department'' means the New Jersey Department of Health and Senior Services.

''Drug Control Unit'' means the administrative unit within the Department of Law and Public Safety, Division of Consumer Affairs, Enforcement Bureau located at PO Box 45045, Newark, NJ 07101.

''Drug Enforcement Administration'' means the United States Department of Justice, Drug Enforcement Administration.

''Executive Officer'' means the administrator of the Drug Control Unit who may be contacted at (973) 504-6545.

8:65-1.2 Registration requirements

(a) Every person who manufactures or proposes to manufacture a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(b) Every person who distributes or proposes to distribute a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration within 30 days of the effective of date of these regulations, and shall obtain a renewal of the registration every year thereafter.

(c) Every person who dispenses (including prescribing, administering, compounding, or delivering) or proposes to dispense a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(d) Every person who conducts research or proposes to conduct research with a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(e) A person desiring to obtain a registration or a renewal of registration as provided in (a) through (d) above shall prepare and file an application in accordance with the procedure set forth in N.J.A.C. 8:65-1.4, accompanied by the annual registration fee as set forth in N.J.A.C. 8:65-1.1.

(f) A separate application shall be made and a separate registration obtained for each place of business or professional practice, where the applicant manufactures, distributes or dispenses controlled dangerous substances. A separate application shall be made and a separate registration obtained for each separate and distinct business entity, affiliated corporation, or subsidiary corporation that engages in such activities, but a single entity doing business at one location under more than one business name or trade name may obtain a single registration provided that all such business names or trade names are stated in the application.

(g) Every person or duly authorized agent who dispenses or proposes to dispense sodium pentobarbital for purposes of animal euthanasia, unless specifically exempted by statute or specifically waived by the Commissioner, shall apply for a registration and shall obtain a renewal of registration every year thereafter.

1. Applications for registration to use sodium pentobarbital for animal euthanasia may be obtained from the Drug Control Unit. Upon receipt of said application by this Unit, the security, safeguards, recordkeeping requirement and personnel training requirements shall be inspected and/or reviewed, and upon satisfactory compliance with the statute and regulations, a registration certificate shall be issued to the applicant.

(h) Every person or duly authorized agent required to register pursuant to (g) above shall be required to provide evidence of a current general liability insurance policy. A certified individual shall be deemed to be acting in behalf of and at the direction of the duly authorized agent.

(i) Every person or duly authorized agent required to register pursuant to (g) above shall be limited to the use of sodium pentobarbital only. Registration granted under (g) above shall not entitle a registrant to buy, possess and/or dispense controlled dangerous substances other than that specified in the registration.

(j) Every individual, as directed by the registered duly authorized agent to use sodium pentobarbital in animal euthanasia, shall be required to be trained in, and demonstrate proficiency with, the use of sodium pentobarbital in animal euthanasia, to the satisfaction of a New Jersey licensed veternarian. Said New Jersey licensed veterinarian shall, in writing and filed with the registered incorporated humane society or licensed animal care facility, so certify the training and demonstrated proficiency of the individual in the use of sodium pentobarbital in animal euthanasia.

(k) Every person or duly authorized agent required to register pursuant to (g) above shall prepare written procedures and protocol, approved by a New Jersey licensed veterinarian, for the administration of sodium pentobarbital in animal euthanasia. Such written procedure and protocol must be on file at the licensed premise and readily available for review by a Drug Control Unit representative.

(*l*) A person or duly authorized agent registered as a dispenser for the purposes of purchasing and dispensing sodium pentobarbital for the purpose of animal euthanasia shall be limited to registration in Schedule II (sodium pentobarbital) and may possess or have under his control such amounts as are reasonably necessary to administer euthanasia on the premises of the registered location.

8:65-1.3 Activities requiring registration

(a) Registration under N.J.A.C. 8:65-1.2(a) or (b) shall be issued to authorize the registrant to manufacture or distribute respectively specific controlled dangerous substances included in Schedule I or Schedule II, or to authorize the registrant to manufacture or distribute respectively the controlled dangerous substances included in Schedules III, IV, or V. Any registrant authorized to manufacture or distribute substances included in Schedules III, IV, or V may manufacture or distribute respectively any controlled dangerous substance listed in the Schedule or Schedules for which he is registered.

(b) A person desiring to obtain a registration under N.J.A.C. 8:65-1.2(a) or (b) shall specify the controlled dangerous substances or the Schedules for which he wishes to obtain a registration in his application and may manufacture or distribute only those controlled dangerous substances authorized in his registration.

(c) Registration under N.J.A.C. 8:65-1.2(c) shall be issued to authorize the registrant to dispense controlled dangerous substances in Schedules II, III, IV, or V by Schedules. Any person desiring to obtain a registration to dispense shall specify the Schedules for which he wishes to be registered in his application and may dispense only those controlled dangerous substances in the Schedules included in his registration.

(d) Every practitioner registered to dispense controlled dangerous substances who desires to conduct research with substances included in Schedule I or with substances included in Schedules II through V shall make a separate application and be issued a separate registration to conduct such research. Such practitioner shall, in addition to the general requirements of these regulations, furnish the Drug Control Unit with a copy or photocopy of his Federal registration or Federal authorization to conduct research with such substances and a copy of the research protocol.

(e) A practitioner registered to dispense controlled dangerous substances may conduct research with nonnarcotic substances in Schedules II through V which are included in his registration without applying for a separate registration to conduct research.

(f) A practitioner not registered to dispense may be registered to conduct research only for the purpose of making a laboratory analysis of substances to determine the presence of controlled dangerous substances. Such registrant may not possess or have under his control any controlled dangerous substance except such amounts as are reasonably necessary to make such analysis on the premises of the registered location.

(g) A person registered to manufacture controlled dangerous substances may distribute those substances which he is authorized to manufacture without obtaining a separate registration, provided that distribution is from the registered location. A person desiring to distribute controlled dangerous substances other than those he is registered to manufacture or from a different location shall obtain a separate registration as a distributor.

(h) For purposes of registration, the following activities by a registrant will not be deemed to require an additional registration for a separate location:

1. An office used by a registered manufacturer or distributor or his agents or employees to solicit or make sales of controlled dangerous substances, provided that no such substances are contained in or distributed from such office.

2. An office used by a registered dispenser where controlled dangerous substances are prescribed, provided that no such substances are administered, delivered, or otherwise dispensed, and no such substances are contained in such office.

(i) A person or duly authorized agent registered as a dispenser for the purchasing and dispensing of Sodium Pentobarbital for the purpose of animal euthanasia shall be limited to registration in Schedule II N (Sodium Pentobarbital) and may possess or have under his control such amounts as are reasonably necessary to administer euthanasia on the premises of the registered location.

8:65-1.4 Registration application

(a) All applications for registration shall be made on forms provided by the Executive Officer and shall be filed with the Drug Control Unit at PO Box 45045, Newark, NJ 07101.

(b) Applications shall contain all information called for on the forms provided, except where such information is not applicable in which case this fact shall be stated.

(c) The Commissioner may require an applicant to submit documents and statements pertinent to the application or may require the applicant to amend the application to make it more definite and certain.

(d) Each application and each additional document or statement required by the Commissioner shall be signed by the applicant, if an individual; by a general partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation or other entity.

(e) Any application may be amended or withdrawn by the applicant as a matter of right prior to the date of service of any order to show cause pursuant to N.J.S.A. 24:21-12. An application may be amended or withdrawn by the applicant after the date of service of such an order to show cause only upon written consent of the Commissioner.

(f) A duplicate copy of each application and of each additional document or statement required pursuant to (c) above shall be kept by the applicant at the location to be registered.

8:65-1.5 Action upon application

(a) After an application for registration has been filed, the Drug Control Unit shall make such inspection of the place of business or professional practice described in the application and such investi-

gation of the applicant as may be necessary to determine that the applicant meets the requirements of the applicable statutes and regulations.

(b) A person lawfully engaged in the manufacture, distribution or dispensing of any controlled dangerous substance prior to January 17, 1971, who was registered or licensed by the State to engage in such activity, may in the discretion of the Commissioner, after making proper application for registration, be issued a registration as to such controlled dangerous substances prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(c) Any application for renewal of a registration issued pursuant to the New Jersey Controlled Dangerous Substances Act and these regulations may in the discretion of the Commissioner be granted and a renewal of registration issued prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(d) The issuance of a registration pursuant to paragraphs (b) or (c) above shall not be deemed to vest any right to continue the registration or to obtain a renewal thereof, if upon subsequent inspection or investigation the Commissioner determines that the registrant does not meet the requirements of the applicable statutes or regulations.

(e) The registration certificate issued hereunder shall be displayed conspicuously in the registered location.

8:65-1.6 Assignment or transfer of registration

(a) No registration nor any right granted thereunder shall be assigned or otherwise transferred to any person not named as the registrant therein nor to any place of business or professional practice not stated therein, except as provided by statute or regulations.

(b) A registrant who changes his place of business or professional practice from the location which is stated in the registration to a new location within the State of New Jersey, without any change in the ownership of the business or professional practice, may obtain an endorsement validating his registration for the remainder of the registration period at the new location by notifying the Commissioner in writing, which notice shall set forth the name and registration number of the registrant, the address of the registered location, the address of the new location, and the effective date of the change of location.

(c) A registration shall terminate and become void if and when the registrant dies, ceases legal existence, or discontinues business or professional practice in the State of New Jersey. A registrant who ceases legal existence or discontinues business or professional practice shall notify the Commissioner in writing and surrender his current registration. In the event that the business or professional practice will be continued or resumed after a change in ownership a new application for registration shall be made pursuant to N.J.A.C. 8:65-1.1 and 1.2 of this Chapter.

(d) For purposes of this section it shall be deemed to be a change of ownership of a business or professional practice in the case of a partnership, and in the case of a corporation if there is a change in the president or chief executive officer of the corporation, or in the ownership of ten per cent or more of the outstanding shares in the corporation.

8:65-1.7 Changes in schedule

Consistent with the provisions set forth in N.J.S.A. 24:21-3, regulations promulgated pursuant to the United States Comprehensive Drug Abuse Prevention and Control Act of 1970, which designate, reschedule or delete a substance as a controlled substance under Federal Law, shall be deemed to be effective under the New Jersey Controlled Dangerous Substance Act (N.J.S.A. 24:21-1 et seq.) 30 days after their effective date of the Federal regulation, unless the Commissioner, within that 30 day period,

shall object to inclusion, rescheduling or deletion, which objection shall thereafter be published in the New Jersey Register.

8:65-1.8 Duplicate registration

Any registrant requesting a duplicate of a certificate of registration shall apply to the Drug Control Unit in writing and pay a fee of $5.00 for such duplicate.

SUBCHAPTER 2. SECURITY REQUIREMENTS

8:65-2.1 Security requirements generally

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department shall use the security requirements set forth in sections 2 through 6 of this subchapter as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in sections 2, 3, and 5 of this subchapter may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in section 2 through 6 of this subchapter may be deemed sufficient by the Department after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Department may consider any of the following factors as may deem relevant to the need for strict compliance with security requirements:

1. The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, co-operative buying, and so forth);
2. The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
3. The quantity of controlled substances handled;
4. The location of the premises and the relationship such location bears on security needs;
5. The type of building construction comprising the facility and the general characteristics of the building or buildings;
6. The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
7. The type of closures on vaults, safes, and secure enclosures;
8. The adequacy of key control systems and/or combination lock control systems;
9. The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
10. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
11. The adequacy of supervision over employees having access to manufacturing and storage areas;

12. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

13. The availability of local police protection or of the registrant's or applicant's security personnel, and;

14. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Sections 2 through 6 of this Subchapter when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in N.J.A.C. 8:65-2.2 through 2.6 may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the Drug Control Unit.

(e) Physical security controls of locations licensed under the New Jersey Uniform Narcotic Drug Act (N.J.S.A. 24:18-1 et seq.) on January 17, 1971, shall be deemed to comply substantially with the standards set forth in N.J.A.C. 8:65-2.2, 2.3 and 2.5. Any new facilities or work or storage area constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Drug Control Unit, shall not necessarily be deemed to comply substantially with the standards set forth in N.J.A.C. 8:65-2.2, 2.3 and 2.5, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Drug Control Unit.

8:65-2.2 Physical security controls for nonpractitioners: storage areas

(a) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas;

1. Where small quantities permit, a safe or steel cabinet:

   i. Which safe or steel cabinet shall have the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 manminutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

   ii. Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

   iii. Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system, which upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve.

2. A vault constructed before, or under construction on, September 1, 1971 which is of substantial construction with a steel door, combination of key lock, and an alarm system; or

3. A vault constructed after September 1, 1971:

i. The walls, floors and ceilings of which vault are constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings;

ii. The door and frame unit of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, ten man-minutes against forced entry, 20 manhours against lock manipulation, and 20 man-hours against radiological techniques;

iii. Which vault, if operations require it to remain open for frequent access, is equipped with a ''day-gate'' which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

iv. The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

v. The door of which vault is equipped with contact switches; and

vi. Which vault has one of the following; complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Department.

(b) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V shall be stored in one of the following secure storage areas:

1. Where small quantities permit, a safe which complies with the requirements set forth in subsection (a)1 of this Section;

2. A vault which complies with the requirements set forth in either subsection (a)2 or 3; or

3. A building or areas located within a building, which building or area:

i. Has walls or perimeter fences of sufficient height and construction to provide security from burglary;

ii. Has substantial doors which may be securely locked during nonworking hours by a multiple position combination or key lock;

iii. Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve; and

iv. In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (that is, returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this Section.

(d) The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(e) A registrant or authorized agent may request an exception from the provisions of this subchapter from the Department, when, due to the bulk volume of the controlled substance, achieving the required level of security may appear to be economically unreasonable or technically infeasible. Upon receipt of a request, the Department will assess the physical arrangements of the present or proposed security system. Based on considerations of public health and safety, the Department may accept a lesser level of security. A final decision of the Department, and the reasons therefore, shall be entered upon the records of the Department and sent to the registrant or authorized agent.

8:65-2.3 Physical security controls for nonpractitioners; manufacturing areas

(a) All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

1. All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If the security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

2. Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area ''limited access'' may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted, provided, that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

3. During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

8:65-2.4 Other security controls for nonpractitioners

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry with the Drug Control Unit to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose suspicious orders of controlled substances. The registrant shall inform the Drug Control Unit of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Drug Control Unit of any theft or loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to (e) below upon discovery of such theft or loss. The registrant shall also complete DDC-52 form regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer, and only in reasonable quantities. Such request must contain the name, address and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Subchapter 6 of this Act shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ''customer'' includes a registrant to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the registrant.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in section 2 of this subchapter. In addition, the registrant shall employ precautions (for example assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (for example, detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil, etorphine hydrochloride, and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

8:65-2.5 Physical security controls for practitioners

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration. The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, at any time.

(d) The registrant shall notify the Drug Control Unit of the theft or loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DDC-52 form regarding such loss or theft.

(e) Carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

(f) This section shall apply to those persons or duly authorized agents registered for the purposes of purchasing and dispensing sodium pentobarbital for animal euthanasia. Safeguards and security to the sodium pentobarbital shall be in compliance with N.J.A.C. 8:65-2.1.

(g) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia shall maintain records and inventories and shall file the reports required by this subchapter.

SUBCHAPTER 3. LABELING AND PACKAGING REQUIREMENTS

8:65-3.1 Scope

Requirements governing the labeling and packaging of controlled substances pursuant to Sections 305 and 1008(d) of the Act (21 U.S.C. 825 and 958(d)) are set forth generally by those Sections and specifically by the Sections of this part.

8:65-3.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Commercial container'' means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term ''commercial container'' does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum or other package in which commercial containers are stored or used for shipment of controlled substances.

''Label'' means any display of written, printed or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

''Labeling'' means all labels and other written, printed or graphic matter upon any controlled substance or any of its commercial containers or wrappers, or accompanying such controlled substance.

''Manufacture'' means the producing, preparation, propagation, compounding or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term ''manufacture'' means a person who manufactures a drug or other substance, whether under a registration or as a manufacturer or under authority of registration as a research or chemical analyst.

8:65-3.3 Symbol required; exceptions

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Department pursuant to N.J.S.A. 24:21-8d) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	Symbol
1. Schedule I	I or C-I;
2. Schedule II	II or C-II;
3. Schedule III	III or C-III;
4. Schedule IV	IV or C-IV;
5. Schedule V	V or C-V;

6. The word ''Schedule'' need not be used. No distinction need be made between narcotic and nonnarcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind studies.

8:65-3.4 Location and size of symbol on label

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedules I through V. The symbol must be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in subsection (a) of this section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visability against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

8:65-3.5 Location and size of symbol on labeling

(a) The symbol shall be prominently located on all labeling other than labels covered by section 4 of this subchapter.

(b) In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

8:65-3.6 Effective dates of labeling requirements

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on May 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of section 3 of this subchapter.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on May 1, 1971, and thereafter transferred to another schedule or is added to any schedule after May 1, 1971, and which is packaged more than 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of section 3 of this subchapter.

(c) The Department may, in the case of any controlled substance, require compliance with the requirements of section 3 of this subchapter within a period of time shorter than required by this section if he finds that public health or safety necessitate an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal and State law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

8:65-3.7 Sealing of controlled substances

(a) On each bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule I or II or of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid covering or wrapper of such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use under Federal law prior to May 1, 1971, shall be deemed acceptable for use under this section.

8:65-3.8 Labeling and packaging requirements for imported and exported substances

(a) The symbol requirements of sections 3 through 6 of this subchapter apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States, as defined to be the several states, the District of Columbia and Puerto Rico.

(b) The symbol requirements of sections 3 through 6 of this subchapter do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States, as defined to be the several states, the District of Columbia and Puerto Rico.

(c) The sealing requirements of section 7 of this subchapter apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States, as defined to be the several states, the District of Columbia, and Puerto Rico.

SUBCHAPTER 4. (RESERVED)

SUBCHAPTER 5. RECORDS AND REPORTS OF REGISTRANTS

8:65-5.1 Scope

Inventory and other records and reports required under Section 307 or Section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those Sections and by the Sections of this part.

8:65-5.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Act'' means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

''Commercial container'' means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term ''commercial container'' does not include any package liner, package insert of other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

''Dispenser'' means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

''Individual practitioner'' means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

''Institutional practitioner'' means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

''Name'' means the official name, common or usual name, chemical name, or brand name of a substance.

''Pharmacist'' means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

''Readily retrievable'' means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. Any term not defined in this section shall have the definition set forth in Sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in N.J.S.A. 24:21-1 et seq.

8:65-5.3 Persons required to keep records and file reports

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activi-

ties without being registered to conduct those activities, either pursuant to N.J.S.A. 24:21-10 or pursuant to N.J.A.C. 8:65-8.4 to 8.8, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities (e.g., when a registered manufacturer conducts chemical analysis, he shall maintain the records and inventories required of chemical analysis).

(b) A registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in schedule II through V which he prescribes in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he administers and dispenses.

(c) A registered individual practitioner is required to keep records with respect to nonnarcotic controlled substances listed in schedules II through V which he dispenses or administers.

(d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under Section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of these sections is not required to keep records if he notifies the Bureau of the name, address, and registration number of the establishment maintaining such records.

(e) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Drug Enforcement Administration and the Drug Control Unit of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by subsections (d) and (e) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

8:65-5.4 Maintenance of records and inventories

(a) Every inventory and other record required to be kept under this subchapter shall be kept by the registrant and be available, for at least two years from the date of such inventory of records, for inspecting and copying by authorized employees of the Drug Enforcement Administration and the Drug Control Unit, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to N.J.A.C. 8:65-6.13) may be kept at a central location, rather than at the registered location, if the registrant has notified the Drug Enforcement Administration and the Drug Control Unit of his intentions to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested to the Special Agent in Charge in the region in which the registrant is located and the Drug Control Unit. Unless the registrant is informed by the Special Agent in Charge or the Drug Control Unit that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge and the Drug Control Unit. Registrants who desire to continue maintaining central recordkeeping will make notification to the local Special Agent in Charge and the Drug Control Unit as provided in this section. All notifications shall include the following:

1. The nature of the records to be kept centrally and the exact location where the records will be kept; the name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally, and whether central records are being maintained in a manual, or computer readable form.

2. If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than for pricing information) a key to the code shall be provided to make the records understandable.

3. The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a request from the Drug Enforcement Administration or the Drug Control Unit for such records, and if the Drug Enforcement Administration or the Drug Control Unit chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Drug Enforcement Administration or the Drug Control Unit to inspect such records at central location upon request by such employees without a warrant of any kind; and

4. In the event that a registrant fails to comply with these conditions, the Special Agent in Charge or the Drug Control Unit may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorization under this paragraph the registrant shall within the time specified by the Special Agent in Charge, or the Drug Control Unit, comply with the requirements of this section that all records be kept at the registered location.

5. Registrants need not notify the Special Agent in Charge or the Drug Control Unit or obtain central recordkeeping in order to maintain records on an in-house computer system.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records and controlled substances as follows:

1. Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrant; and

2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(c) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in subsection (b) of this section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in schedules III, IV, and V only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter ‘‘C’’ no less than one-inch high and filed either in the

prescription file for controlled substances listed in schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

(e) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia and required to keep records shall maintain inventories and records of controlled substances in the manner prescribed in subsection (b) of this section.

8:65-5.5 General requirements for inventories

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be ''on hand'' if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in section 12 of this subchapter.

(d) A registrant may take an inventory on a date that is within four days of his biennial inventory date pursuant to N.J.A.C. 8:65-5.7 if he notifies in advance the Special Agent in Charge of the Drug Enforcement Administration in his region and the Drug Control Unit of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory was taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

8:65-5.6 Initial inventory date

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with sections 9 through 13 of this subchapter as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with sections 9 through 13 of this subchapter, as applicable.

8:65-5.7 Biennial inventory date

Every two years following the date on which the initial inventory is taken by a registrant pursuant to N.J.A.C. 8:65-5.6, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply. If the registrant

elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Drug Enforcement Administration and the Drug Control Unit of this election and of the date on which the biennial inventory will be taken.

8:65-5.8 Inventory date for newly-controlled substances

On the effective date of a rule by the Drug Enforcement Administration Administrator pursuant to 308.48, 308.49 or 308.50 of the Act or the Department pursuant to N.J.S.A. 24:21-3 adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substances shall be included in each inventory made by the registrant pursuant to N.J.A.C. 8:65-5.7.

8:65-5.9 Inventories of manufacturers

(a) Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(a) to manufacture controlled substances shall include the following information to his inventory:

1. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in the finished form:

   i. The name of the substance; and

   ii. The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

2. For each controlled substance in the process of manufacture on the inventory date:

   i. The name of the substance;

   ii. The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;

   iii. The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number or volume thereof; and

3. For each controlled substance in finished form:

   i. The name of the substance;

   ii. Each finished form of the substance (e.g., ten-milligram tablet or tem-milligram concentration per fluid ounce or milliliter);

   iii. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial); and

   iv. The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six three-milliliter vials).

4. For each controlled substance not included in paragraphs (1), (2) or (3) of this subsection (e.g.,

damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounds):

i. The name of the substance;

ii. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

iii. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

8:65-5.10 Inventories of distributors

Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(a) to distribute controlled substances shall include in his inventory the same information of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4.

8:65-5.11 Inventories of dispensers and researchers

(a) Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(d) to dispense or conduct research with controlled substances and required to keep records pursuant to N.J.A.C. 8:65-5.3, shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

1. If the substance is listed in schedule I or II, he shall make a count or measure of the contents; and

2. If the substance is listed in schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

(b) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia and required to keep records, shall maintain a quarterly inventory (last day of March, June, September, December) on forms provided by the Drug Control Unit in the manner prescribed in (a) above. A copy of such inventory shall be received in the Drug Control Unit within seven days after such required report is completed.

8:65-5.12 Inventories of importers and exporters

(a) Each person registered or authorized (by 301-22(b) of this Chapter) to import or export controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)1, 3 and 4.

(b) Each such person who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

8:65-5.13 Inventories for chemical analysts

(a) Each person registered or authorized (by 301.22(b) of the Act) and N.J.A.C. 8:65-1.3 to conduct chemical analysis with controlled substances shall include in his inventory the same information

required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)1, 3 and 4, as to substances which have been manufactured, imported or received by such person.

(b) If less than one kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

(c) Laboratories of the Drug Enforcement Administration may possess up to 150 grams of any hallucinogenic substance in schedule I without regard to a need for an inventory of those substances.

(d) No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

8:65-5.14 General requirements for continuing records

(a) On and after May 1, 1971, every registrant required to keep records pursuant to Section 3 of this Subchapter shall maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in Section 4(a) of this Subchapter. In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in Sections 18 and 19 of this Subchapter.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

8:65-5.15 Records of manufacturers

(a) Each person registered or authorized (by 301.22(b) or 307.15 of the Act) and N.J.A.C. 8:65-1.3(a) to manufacture controlled substances shall maintain records with the following information:

1. For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

   i. The name of the substance;

   ii. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

   iii. The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

   iv. The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity, and import permit or declaration number for each importation;

v. The quantity used to manufacture the same substance in finished form, including:

(1) The date and batch or other identifying number of manufacture;

(2) The quantity used in the manufacture;

(3) The finished form (such as, ten-milligram tablets or tenmilligram concentration per fluid ounce or milliliter);

(4) The number of units of finished form manufactured;

(5) The quantity used in quality control;

(6) The quantity lost during manufacturing and the cause therefor, if known;

(7) The total quantity of the substance contained in the finished form;

(8) The theoretical and actual yields; and

(9) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

vi. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subparagraph v. of this Section;

vii. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

viii. The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

ix. The quantity distributed in any other manner by the registrant (such as, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed of.

2. For each controlled substance in finished form,

i. The name of the substance;

ii. Each finished form (such as, ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (such as, 100-tablet bottle or three-milliliter vial);

iii. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph 1v of subsection (a) of this Section;

iv. The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

v. The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

vi. The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(1) The date and batch or other identifying number of each manufacture;

(2) The operation performed (such as, repackaging or relabeling);

(3) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(4) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

vii. The number of commercial containers distributed to other persons, including the date of an number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

viii. The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each expiration; and

ix. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (such as, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed of.

8:65-5.16 Records for distributors

(a) Each person registered or authorized (by 301.22(b) or 307.11-307.14 of the Act) and N.J.A.C. 8:65-1.3(a) to distribute controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;

2. Each finished form (such as, ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (such as, 100-tablet bottle or three-milliliter vial);

3. The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

4. The number of commercial containers or each such finished form imported directly by the person (under a registration or authorization to import), including the date of, the number of commercial containers in, and the import permit or declaration number for, each importation;

5. The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address, and registration number of the person to whom the containers were distributed;

6. The number of commercial containers of each such finished form exported directly by the person (under a registration or authorization to export), including the date of, the number of commercial containers in, and the export permit or declaration number for, each exportation; and

7. The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the person (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

8:65-5.17 Records for dispensers and researchers

(a) Each person registered or authorized (by 301.22(b) of the Act) and N.J.A.C. 8:65-1.3(e) to dispense or conduct research with controlled substances and required to keep records pursuant to Section 3 of this subchapter shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial);
3. The number of commercial containers of each such finished form received from other persons, including the date and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;
4. The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and
5. The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed

(b) Each person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia shall make, keep and maintain records of the use of sodium pentobarbital on forms provided by the Drug Control Unit.

8:65-5.18 Records for importers

(a) Each person registered or authorized (by 301.22(b) of the Act) to import controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;
3. The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and
4. The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to N.J.A.C. 8:65-5.15(a)4 or (b)5, including the date and manner of disposal and the quantity disposed.

8:65-5.19 Records for exporters

(a) Each person registered or authorized (by 301.22(b) of the Act) to export controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;
3. The quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to N.J.A.C. 8:65-5.15(a)1viii or 2viii; and
4. The quantity disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity disposed.

8:65-5.20 Records for chemical analysts

(a) Each person registered or authorized (by 301.22(b) of the Act) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

1. The name of the substance;
2. The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., ten-milligram tablet or ten-milligram concentration per milliliter);
3. The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty one-milliliter vials, or ten grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;
4. The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported. (b) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known, or suspected, controlled substances received as evidentiary material for analysis are not required under paragraph (a) of this Section.

8:65-5.21 Reports from manufacturers and importers

(a) Each registered manufacturer and registered importer shall submit a quarterly report (D.E.A. Form 333) accounting for all stocks of narcotic controlled substances listed in schedules I, II and III on hand at the beginning and end of the quarter, and for all receipts (D.E.A. Form 333), dispositions (D.E.A. Form 333), manufacturing (D.E.A. Form 333) and packaging (D.E.A. Form 333), of such substances on the appropriate Federal forms. The returns shall be obtained from and submitted to

the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, D.C. 20537, on or before the 15th day of the month succeeding the period for which it is submitted.

(b) All narcotic controlled substances listed in schedules I, II, and III received by a manufacturer or importer, shall be recorded on D.E.A. Form 333 in order and at the time of receipt. Where record on D.E.A. Form 333 cannot, for any good and sufficient reason, be made immediately, the manufacturer or importer shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I, II, and III by a manufacturer or importer, including exporters, distributors, and losses shall be recorded on D.E.A. Form 333.

1. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet, separate entries shall be used to report dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

2. The details of all exports and all domestic distribution of narcotic controlled substances shall be reported in full on D.E.A. Form 333, except that the details of distribution of narcotic controlled substances listed in schedule III sold to dispensers shall be included in summarized entries on D.E.A. Form 333.

3. For all such distributions not reported on detail, the manufacturer shall have available for inspection original sales orders, delivery slips, or other papers or records sufficient to fully evidence and explain the dispositions.

(d) All narcotic controlled substances listed in schedules I, II and III used in the production of other drugs or preparations, with the exception of transactions involving original manufacture from raw opium or coca leaves, shall be entered on D.E.A. Form 333 in the order and at the time they are placed into the process of manufacture. All narcotic controlled substances listed in schedules I, II, and III and preparations produced therefrom shall be entered on the same form, at the time of production, which entry shall be clearly identified with the entry of substances used in their production.

1. Where record of ''Used for Production'' or ''Production'' cannot be made immediately, the manufacturer shall have available such batch tags, production orders, or other papers as may be required to evidence any unrecorded quantity used or produced.

2. Any loss in manufacture, and any recoverable wastes salvaged from the manufacturer shall be reported. All wastes shall be returned to raw stock and included in the report of raw materials on hand at the end of the month.

3. Any narcotic controlled substance listed in schedules I, II, and III actively in process of manufacture at the end of the month shall be so reported. Where substances are placed in process during one quarter and a portion of the production is removed from process as finished goods during the same quarter, the portion thus removed from process shall be reported ''Produced'' and the remainder reported as ''In process'' at the close of the period.

4. Narcotic controlled substances listed in schedules I, II, and III placed in process for the manufacture or narcotic controlled substances listed in schedule V shall be reported on a separate D.E.A. Form 333, on which the kind and quantity of narcotic used and the name of the substance to be produced therefrom shall be stated.

(e) All narcotic controlled substances listed in schedules I, II, and III, either bulk finished goods or goods already packaged, which are used during the quarter for packaging or repackaging into commercial containers shall be reported as credit entries in the D.E.A. Form 333, and in each instance clearly identified with the entry of the substance used in such packaging. A separate entry shall be made for each different size of commercial container produced, but all entries representing a single packaging lot shall be grouped together.

1. The number of commercial containers of a given size produced, the size of the commercial container (indicating the number of pills, tablets, ounces, and so forth), the narcotic controlled substance contained in each unit in the commercial container, the total narcotic controlled substance content of each container, and the aggregate narcotic controlled substance content of all commercial containers, represented by the entry shall be indicated.

2. The recoverable wastes salvaged from the packaging operation and the losses in packaging shall be shown as credit entries on the form. All recoverable wastes reported during the quarter shall be returned to raw stock and further accounted for as raw materials.

3. Any goods actively in process of packaging at the close of the quarter shall be so reported. Where substances are placed in process of packaging during one quarter and a portion thereof are removed as commercial containers, produced during the same quarter, the portion thus removed shall be reported as commercial containers produced and the remainder reported as in process at the end of the quarter.

(f) Each manufacturer and importer shall submit as a part of his fourth quarterly report (D.E.A. Form 333) an inventory (D.E.A. Form 333) of narcotic controlled substances listed in schedules I, II, and III which are in possession on December 31 of each year. The substances shall be classified as follows:

1. Raw materials;

2. Goods in process;

3. Finished bulk stock;

4. Finished goods in marketable commercial containers;

5. Miscellaneous stock.

8:65-5.22 Reports of distributors and exporters

(a) Every registered distributor except any officer or agency of the Veteran's Administration or who or which is exempted from registration pursuant to 301.25 of the Act and N.J.A.C. 8:65-1.3 and registered exporter shall submit a monthly report on D.E.A. Form 333 and its supplement accounting for all transactions involving narcotic controlled substances listed in schedules I and II, including all receipts (D.E.A. 333) and dispositions (D.E.A. Form 333). The report shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 25037, on or before the 15th day of the month succeeding that for which the return is submitted.

(b) All narcotic controlled substances listed in schedules I and II received by a distributor or exporter shall be recorded on D.E.A. Form 333 in order and at the time of receipt. Where a record of D.E.A. Form 333, such form cannot, for any good and sufficient reason, be made immediately, the distributor or exporter shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I and II, including distributions, exports, losses shall be reported on D.E.A. Form 333. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet, separate entries shall be made of dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

(d) Each distributor and exporter shall submit, as part of his December 31 month report on D.E.A. Form 333 and its supplements, any inventory on D.E.A. Form 333 of the narcotic controlled substances listed in schedules I and II which are in his possession on December 31 of each year. A separate entry shall be made for each narcotic substance as follows:

1. The name, quantity, and narcotic content of the drug or preparation;
2. The size of each commercial container; and
3. The number of commercial containers.

(e) The distributor and exporter shall report on D.E.A. Form 333 complete summary of transactions for the month.

8:65-5.23 Reports from manufacturers importing opium

(a) Every manufacturer importing crude opium shall submit, in addition to the report on D.E.A. Form 333 and its supplements, D.E.A. Form 247 and its supplements 247a and 247b, accounting for the importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, U.S. Pharmacopoeia/National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations shall be accounted for in the quarterly returns on D.E.A. Form 333 and its supplements, D.E.A. Form 247 and its supplements and shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 20537 on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from crude opium shall consist of summaries (D.E.A. Forms 247 and 247a) with supporting detail sheets (D.E.A. Form 247b) accounting for original manufacture from crude opium, production from morphine for further manufacture and production from manufacturing opium, and also accounting for stocks of crude opium, manufacturing opium, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (D.E.A. Form 247b) supporting the summary of original manufacture from crude opium shall show separately the crude opium used for the manufacture of opium tinctures and extracts, crude opium used for the extraction of alkaloids, crude opium used for the manufacturing of controlled substances, listed in schedule V, and crude opium used for the production of manufacturing opium; and shall show separately the medicinal opium, alkaloids and salts, opium tinctures and extracts, controlled substances listed in schedule V, and manufacturing opium produced.

(d) Importation of opium shall be reported in summarized entries in the debit summary of quarterly report (D.E.A. Form 333) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (D.E.A. Form 333) as transferred to importing manufacturing report. Such importations shall be further reported in summary (D.E.A. Form 247) and supporting detail sheets (D.E.A. Form 247b). Products manufactured therefrom shall be reported as produced in accordance with (b) and (c) above, and, with the exception of manufacturing opium, morphine for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (D.E.A. Form 333) required when reported produced.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. These assays shall be accounted for in terms of its anhydrous morphine alkaloid content. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Upon withdrawal of crude opium from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the opium will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(h) Opium products and derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Medicinal opium, morphine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Medicinal opium, tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) Subject to N.J.A.C. 8:65-4.8(c), no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(j) In making conversions of opium alkaloids and their salts to anhydrous morphine, the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia..

8:65-5.24 Reports of manufacturer importing medicinal coca leaves

(a) Every manufacturer importing raw coca leaves for the manufacture of medicinal products shall submit, in addition to the report on D.E.A. 333 and its supplements, additional forms and their supplements required for accounting for the importation and for all manufacturing operations performed between importation and the manufacture of bulk or finished products standardized in accordance with the U.S. Pharmacopoeia/National Formulary, or other recognized standards. Subsequent manufacture from such products, including bottling or packaging operation, shall be accounted for in quarterly reports on D.E.A. Form 333 and its supplements. Reports on D.E.A. Form 168 and its supplements shall be submitted quarterly to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from medicinal coca leaves shall consist of summaries (D.E.A. Forms 168 and 168a) with supporting detail sheets (D.E.A. Form 168b) accounting for original manufacture from such leaves, conversions or production from manufacturing coca extracts, and also accounting for stocks of raw coca leaves, manufacturing coca extracts, and other crude coca alkaloids.

(c) The detail sheets (D.E.A. Form 168b) supporting the summary of original manufacture from medicinal coca leaves, shall show separately the coca leaves used for the manufacture of manufacturing coca tinctures and extracts, and coca leaves used for the extraction of alkaloids, and shall show separately the coca alkaloids and salts, coca tinctures and extracts, and manufacturing coca extracts produced.

(d) Importation of medicinal coca leaves shall be reported in summarized entries in the debit summary of the quarterly report (D.E.A. Form 333) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (D.E.A. Form 333) as transferred to importing manufacturer's report. Such importation shall be further reported in summary (D.E.A. Form 168) and supporting detail sheets (D.E.A. Form 168b). Products manufactured therefrom shall be reported in accordance with subsection (h) of this section and, with the exception of manufacturing coca extracts, residues or bases for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (D.E.A. Form 333) when reported produced.

(f) Upon withdrawal of medicinal coca leaves from customs custody, the importing manufacturer shall assign to each bale or container an identification mark or number by which the coca leaves will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(h) Manufacturing coca extracts shall be reported as produced when they come into existence in that form in which they are intended for exclusive use in further manufacture. Cocaine and its salts, ecgonine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product is ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture shall be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) No accumulations of cocaine or ecgonine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks and reported as produced.

(j) In making conversions of coca alkaloids and their salts to cocaine alkaloid and to anhydrous ecgonine alkaloid, the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the molecular weight of such alkaloid or salt and the molecular weight of cocaine alkaloid (303.172) or anhydrous ecgonine alkaloid (185.125), as the case may be, such weights being computed to the third decimal place from the chemical formulae of the substances and the

atomic weights of the elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S.

8:65-5.25 Reports from manufacturers importing special coca leaves

(a) Every manufacturer using special coca leaves imported into the United States shall submit a quarterly report (D.E.A. Form 249) accounting for all transactions involving such leaves or substances derived therefrom which contain cocaine or ecgonine, or any salts, derivatives, or preparations from which cocaine or ecgonine may be synthesized or made. This report shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, D.C. 20537, on or before the 15th day of the month following the period for which the report is made. Such report shall include a report of all importations of special coca leaves (D.E.A. Form 249a), a report of all materials entered into the processes of manufacturer, a report of the various substances produced therefrom (D.E.A. Form 249c, 249d and 249e), a report of all such substances destroyed (D.E.A. Form 249f), and a summary of operations (D.E.A. Form 249g).

(b) The report of importations shall provide in appropriate columns the following data as to each importation:

1. The date of the import permit;
2. The serial number of the import permit;
3. The name of the foreign consignor;
4. The address of the foreign consignor;
5. The foreign port of export;
6. The number of bales imported;
7. The serial numbers of the bales imported; and
8. The quantity imported in avoirdupois pounds.

(c) The report of materials entered into the process of manufacture shall provide in appropriate columns the following information as to each lot of leaves dumped:

1. The lot number of specification, a specification to be assigned to each dump for identification purposes in order to avoid repeating the serial numbers of the bales when the lot is subsequently referred to;
2. The date the leaves entered into the process of manufacture;
3. The number of bales dumped;
4. The serial numbers of the bales;
5. The quantity of leaves entered into the process of manufacture, stated in avoirdupois pounds;
6. The quantity of alcohol used for each extraction or wash of the leaves;
7. The quantity of water used for each water extraction or dilution;
8. The quantity of any other or additional substance introduced at any stage into the process of manufacture; and
9. The dry weight of any filter cloth or other absorbent material to be later removed from the process after saturation.

(d) The reports of substances produced from special coca leaves shall provide in columns the following information as to each production lot or dump:

1. The lot number;
2. The quantity of ground leaves entered into process, in terms of avoirdupois ounces and the quantity, in ounces and grains, of alkaloid contained therein as determined by analysis;
3. The quantity of substance in process after each distinct step in the manufacturing process and the total alkaloid contained in each, stated in ounces and grains;
4. The quantity of exhausted or spent leaves and the quantity of each residue removed from process, and the total alkaloid contained in each, stated in ounces and grains;
5. The weight of the used filter cloth or other absorbent material removed, after saturations; and
6. The quantity, in gallons, of finished extract produced.

(e) The report of substances destroyed, shall provide in appropriate columns the following data as to each lot destroyed:

1. The lot numbers;
2. The quantity of spent leaves, residues, and saturated materials destroyed, stated separately for each; and
3. The name of the Government officer witnessing the destruction.

(f) The summary shall include a complete accounting for all transactions in raw leaves, leaves in process, and residues removed from production processes.

1. The summary of raw coca leaves shall include:
   i. The quantity of special coca leaves on hand at the beginning of the quarter;
   ii. The quantity of special coca leaves imported during the quarter;
   iii. The quantity of special coca leaves entered into the process of manufacture during the quarter;
   iv. The quantity of special coca leaves on hand at the end of the quarter; and
   v. Any other transaction during the quarter which increased or decreased the quantity of raw coca leaves on hand.
2. The summary of coca leaves in process shall include:
   i. The quantity of special coca leaves in process at the beginning of the quarter;
   ii. The quantity of such leaves placed in the process during the quarter;
   iii. The quantity of such leaves represented by lots completed during the quarter;
   iv. The quantity of such leaves represented by lots in process at the end of the quarter; and
   v. Any other transaction during the quarter which increased or decreased the quantity of leaves in process.

3. The summary of residues removed from production processes shall provide in appropriate columns, separately as to spent leaves, each residue and saturated material, the following information:

i. The quantity of each, on hand at the beginning of the quarter, awaiting destruction;

ii. The quantity of each removed from process during the quarter;

iii. The quantity of each destroyed during the quarter;

iv. The quantity of each on hand at the end of the quarter; and

v. Any other transaction during the quarter affecting the quantity of such residues on hand.

SUBCHAPTER 6. ORDER FORMS

8:65-6.1 Scope

This subchapter sets forth the Federally mandated requirements governing the issuance, use, and preservation of order forms pursuant to the Controlled Substances Act (21 U.S.C. 828, section 308).

8:65-6.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the contents clearly indicate otherwise: ''Act'' means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and the Controlled Substance Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

''D.E.A.'' means the Drug Enforcement Administration.

''Purchaser'' means any registered person entitled to obtain and execute order forms pursuant to N.J.A.C. 8:65-6.4 and 6.

''Supplier'' means any registered person entitled to fill order forms pursuant to N.J.A.C. 8:65-6.8.

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and 301.02 and 302.02 of the Act, or N.J.S.A. 24:21-1 et seq.

8:65-6.3 Distribution requiring order forms

(a) An order form (DEA Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

1. The exportation of such substances from the United States in conformity with the Act;

2. The delivery of such substances to or by a common or contract carrier for carriage in the law and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business (but excluding such carriage or storage by the owner of the substance in connection with the distribution of a third person);

3. The procurement of a sample of such substances by an exempt law enforcement official pursuant to 316.04(d) of the Act, provided that the receipt required by that section is used and is preserved in the manner prescribed in this part for order forms;

4. The procurement of such substances by a civil defense or disaster relief organization, pursuant to 301.27 of the Act, provided that the civil defense emergency order form required by that section is used and is preserved with other records of the registrant; and

5. The purchase of such substances by the master of a vessel pursuant to 310.28(a)(3) of the Act; provided, that the special order form provided by the U.S. Public Health Service required by that section is used and preserved in the manner prescribed in this order form.

8:65-6.4 Persons entitled to obtain and execute order forms

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in, schedules I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his registration as to the substances being purchased has not expired or been revoked or suspended.

8:65-6.5 Procedure for obtaining order forms

(a) Order forms are issued in groups of 21 forms, each form containing an original, duplicate, and triplicate copy (respectively, copy 1, copy 2 and copy 3). A limit of 21 forms will be furnished on any requisition, unless additional quantities are specifically requested and a reasonable need for such additional quantity is shown.

(b) Any person applying for a registration which would entitle him to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him to obtain order forms may requisition such forms for the first time on DEA Form 222d, which may be obtained from the Registration Branch of the Administration. All requisitions shall be submitted to the Registration Branch, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the quantity of forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to N.J.A.C. 8:65-6.7.

(d) Order forms will be serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Branch of the Administration by returning the forms with notification of the error.

8:65-6.6 Procedure for executing order forms

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222c. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. There are 10 lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil, etorphine hydrochloride and diprenorphine shall list only these substances. The total number of items ordered shall be noted on that form in the space provided.

(c) An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item the form shall show the name of the article ordered, the finished or bulk form of the article (e.g., ten milligram

tablet, ten-milligram concentration per fluid ounce or milliliter, or United States Pharmacopeia), the number of units or volume in each commercial or bulk container (e.g., 100-tablet bottle of three-milliliter vial) or the quantity or volume of each bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the article if not in pure form. The catalog number of the article may be included at the discretion of the purchaser.

(d) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any one form.

(e) Each order form shall be signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to N.J.A.C. 8:65-6.5(c). The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all executed forms are delivered promptly to the registered location.

(f) The registered agent of a Humane Society or licensed animal shelter may apply for Federal purchase order forms as described in N.J.A.C. 8:65-6.4 and 8:65-6.5. Execution of the order forms shall be as specified in (a) through (e) above.

8:65-6.7 Power of attorney

(a) Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his behalf by filing a power of attorney with records of the registrant.

(b) The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and shall contain the signature of the individual being authorized to obtain and execute order forms, which individual shall affirm his signature.

(c) Any power of attorney may be revoked at any time by filing a notice of revocation, signed by the person who signed the power of attorney.

(d) It shall be necessary to submit a new power of attorney upon the registration of a purchaser only if the application for reregistration was signed by a person different from the person who signed the existing power of attorney.

8:65-6.8 Persons entitled to fill order forms

(a) An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in schedules I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

1. A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration may dispose of any controlled substances listed in schedule I or II in his possession pursuant to order forms in accordance with N.J.A.C. 8:65-8.7;

2. A person who has obtained any controlled substance in schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person; and

3. A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, N.J.A.C. 8:65-8.4;

4. A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to off-site narcotic treatment programs only.

8:65-6.9 Procedure for filling order forms

(a) The purchaser shall submit copy 1 and copy 2 of the order form to the supplier, and retain copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in (f) below.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the D.E.A. on the order form, except as specified in (f) below.

(d) The supplier shall retain copy 1 of the order form for his own files and forward copy 2 to the Regional Director of the D.E.A. in the region in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services established within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

8:65-6.10 Procedure for endorsing order forms

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in N.J.A.C. 8:65-6.9 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he desires to do so, in accordance with N.J.A.C. 8:65-6.9(b), (c) and (d), including shipping all substances directly to the purchaser.

(b) Distribution made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

8:65-6.11 Unaccepted and defective order forms

(a) No order form shall be filled if it:

1. Is not complete, legible, or properly prepared, executed or endorsed; or
2. Shows any alteration, erasure, or change of any description. (b) If an order form cannot be filled for any reason under this Section, the supplier shall return copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, copies 1 and 2 of the order form and the statement shall be attached to copy 3 and retained in the files of the purchaser in accordance with N.J.A.C. 8:65-6.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

8:65-6.12 Lost and stolen order forms

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with copy 3 of the order form first executed. A copy of the statement shall be attached to copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof ''Not accepted'' and return copies 1 and 2 to the purchaser, who shall attach it to copy 3 and the statement.

(b) Whenever any used or unused forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Branch, Drug Enforcement Administration, Department of Justice, PO Box 28083, Central Station, Washington, D.C. 20005, and the Drug Control Unit stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers.

(c) If an entire group of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such group, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the registration branch of the Drug Enforcement Administration and the Drug Control Unit shall immediately be notified.

8:65-6.13 Preservation of order forms

(a) The purchaser shall retain copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain copy 1 of each order form which he has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, he must retain copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to N.J.A.C. 8:65-6.6(e)) at the registered location printed on the order form.

(d) The supplier of carfentanil, etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other forms and records required to be maintained by the registrant.

8:65-6.14 Return of unused order forms

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to 301.45 or 301.46 of the Act as to all controlled substances listed in schedules I and II for which he is registered, he shall return all unused order forms for such substance to the nearest office of the Administration.

8:65-6.15 Cancellation and voiding of order forms

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on copies 1 and 2 of the order form by drawing a line through the cancelled items and printing ‘‘canceled’’ in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in (a) above.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

8:65-6.16 Special procedure for filling certain order forms

(a) The purchaser of carfentanil, etorphine hydrochloride or diprenorphine shall submit copy 1 and 3 of the order form to the supplier and retain copy 3 in his or her own files.

(b) The supplier, upon determining that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the D.E.A. to handle these substances, shall fill the order in accordance with the procedures set forth in 21 C.F.R. 1305.09 except that:

1. Order forms for carfentanil, etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities; and

2. The substances shall only be shipped to the purchaser at the location printed by the D.E.A. upon such order forms under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES

8:65-7.1 Scope

Rules governing the issuance, filling and filing of prescriptions are set forth specifically by the sections of this subchapter.

8:65-7.2 Definitions

The following words and terms when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Act'' means the New Jersey Controlled Substances Act (N.J.S.A. 24:21-1 et seq.).

''Federal Act'' means the Controlled Substances Act (Title 21, United States Code 801: 84 Stat. 1242).

''Individual practitioner'' means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which he practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

''Institutional Practitioner'' means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which it practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

''Pharmacist'' means any pharmacist licensed by the State of New Jersey to dispense controlled substances and shall include any other person (e.g., a pharmacist intern authorized by the State to dispense controlled substances under the provision of a pharmacist licensed by the State).

''Prescription'' means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

''Register'' and ''registered'' refer to registration required and permitted by Section 10 of the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21-10). Any term not defined in this section shall have the definition set forth in the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21-1 et seq.).

8:65-7.3 Persons entitled to issue prescriptions

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and 2. Either registered or exempted from registration pursuant to the Code of Federal Regulations, Title 21, part 1301.24(c) or 1301.25.

(b) A prescription issued by an individual practitioner shall be communicated to a pharmacist by the individual practitioner.

8:65-7.4 Purpose of issue of prescription

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of Law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be used for the dispensing of narcotic drugs listed in any schedule for ''detoxification'' or ''maintenance treatment'' as defined in N.J.A.C. 8:65-11.1.

8:65-7.5 Manner of issuance of prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (for example, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written in ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by a secretary or agent of the practitioner for the signature of the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law or rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules.

(b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veteran's administration facility, exempted from registration under the Code of Federal Regulations, Title 21, part 1301.24(c) shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in the Code of Federal Regulations, Title 21, part 1301.24(c), in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under the Code of Federal Regulations, Title 21, part 1301.25 shall include on all prescriptions issued by him, his branch of service or agency (e.g., ''U.S. Army'' or ''Public Health Service'') and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, or handprinted on it, as well as the signature of the officer.

8:65-7.6 Persons entitled to fill prescriptions

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

8:65-7.7 Administering or dispensing of narcotic drugs

(a) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for ''detoxification treatment'' or ''maintenance treatment'' as defined in N.J.A.C. 8:65-11.1 shall be deemed to be within the meaning of the term ''in the course of professional practice or research''; provided that the practitioner is separately registered with the Drug Control Unit as required by N.J.A.C. 8:65-11.2 and then thereafter complies with the regulatory standards imposed relative to treatment qualifications, security, records and unsupervised use of drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

8:65-7.8 Requirements of prescriptions; schedule II

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in subsection (d) of this section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to N.J.A.C. 8:65-7.6.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in the Code of Federal Regulations, Title 21, part 290.10, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period not to exceed 72 hours (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in N.J.A.C. 8:65-7.4, except for the signature of the prescribing individual practitioner;

3. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

4. Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed (not to exceed the amount for a 72 hour period) to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of N.J.A.C. 8:65-7.4, the prescription shall have written on its face ''Authorization for Emergency Dispensing,'' and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced

to writing. The pharmacist shall notify the Drug Control Unit and the nearest office of the DEA in his district if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense with a written prescription of a prescribing individual practitioner.

(e) A practitioner shall not prescribe or dispense a schedule II controlled substance to an individual patient in excess of the limits set forth at N.J.A.C. 13:35-7.6, except that prescriptions for patients in a Long Term Care Facility (LTCF) may be in amounts as set forth in N.J.A.C. 8:65-7.10(d).

8:65-7.9 Refilling prescriptions; schedule II

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

8:65-7.10 Partial filling of prescriptions; schedule II

(a) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).

(b) The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner.

(c) No further quantity may be supplied beyond 72 hours without a new prescription.

(d) Prescriptions for schedule II controlled substances written for patients in a Long Term Care Facilities (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and practitioner shall assure that a controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is ''terminally ill'' or an ''LTCF'' patient. A prescription that is partially filled and does not contain the notation that the patient is ''terminally ill'' or a patient in a ''LTCF'' shall be deemed to have been filled in violation of N.J.S.A. 24:21. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist shall determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF, or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

(e) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage form, strength and quantity), listing of partial fillings that have been dispensed under

each prescription and the information required in (d) above;

2. Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

3. Retrieval of partially filled schedule II prescription information in accordance with procedures specified in N.J.A.C. 8:65-7.14(e)1 through 5 for schedule III and IV prescription refill information.

8:65-7.11 Labeling of substances; schedule II

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label, conforming to the provisions set forth in N.J.S.A. 24:21-17.

(b) The requirements of (a) above do not apply where a controlled substance listed in schedule II is prescribed for administration to an ultimate user who is institutionalized: Provided, that:

1. Not more than a seven day supply of the controlled substance listed in schedule II is dispensed at one time;

2. The controlled substance listed in schedule II is not in the possession of the ultimate user prior to the administration; and

3. The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in schedule II; and

4. The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

8:65-7.12 Filing of prescriptions; schedule II

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of N.J.A.C. 8:65-5.17.

8:65-7.13 Requirements of prescriptions; schedule III and IV

(a) A pharmacist may dispense directly a controlled substance listed in schedule III or IV which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, pursuant to a written prescription of a duly registered individual practitioner.

(b) A pharmacist may dispense directly a controlled substance listed in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in N.J.A.C. 8:65-7.5(a) except for the signature of the prescribing individual practitioner.

(c) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to section 6 of this subchapter.

(d) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III or IV pursuant to an oral prescription made by a prescribing individual practitioner, or pursuant to an order for medication made by an individual user, subject to section 7 of this subchapter.

8:65-7.14 Refilling of prescriptions; schedules III and IV

(a) No prescription for a controlled substance listed in schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription (or on another appropriate uniformly maintained, readily retrievable record, such as medication records), which indicates by the number of the prescription the following information:

1. The name and dosage of the controlled substance;
2. The date of each refilling;
3. The quantity dispensed;
4. The identity or initials of the dispensing pharmacist in each refilling; and
5. The total number of refills for that prescription, initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed.

(c) If the pharmacist merely initials and dates the back of the prescription he shall be deemed to have dispensed a refill for the full face amount of the prescription.

(d) Additional quantities of controlled substances listed in schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in section 13 of this subchapter which shall be a new and separate prescription.

(e) As an alternative to the procedures provided by (a) through (d) above, an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

1. Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, date of first filing, full name and address of the patient, name and address of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (or the quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.
2. Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.
3. Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal

document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 48 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

4. Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act, and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specific strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name and identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours and if a representative of the Drug Control Unit request a copy of such printout from the user pharmacy, it must, if requested to do so by the representative of the Drug Control Unit verify the printout transmittal capability of its system by documentation (for example, postmark).

5. In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(f) When filing refill information for original prescription orders for schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in this section.

(g) Any registrant who intends to use a system provided by (e) through (f) above must first apply for a Permit to Maintain Central Records as required by the Drug Control Unit.

(h) The transfer of original prescription information for a controlled dangerous substance listed in schedule III or IV for the purpose of refill dispensing is permissible between pharmacies on a one time basis subject to the following requirements:

1. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

   i. Write the word ''VOID'' on the face of the invalidated prescription;

   ii. Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information;

   iii. Record the date of the transfer and the name of the pharmacist transferring the information.

2. The pharmacist receiving the transferred prescription information shall reduce to writing the following:

i. Write the word ‘‘TRANSFER’’ on the face the prescription;

ii. Provide all information required to be on a prescription pursuant to N.J.S.A. 24:21-17 and include:

(1) Date of issuance of original prescription;

(2) Original number of refills authorized on original prescription;

(3) Date of original dispensing;

(4) Number of valid refills remaining and date of last refill;

(5) Pharmacy’s name, address and DEA registration number and original number from which the prescription information was transferred;

(6) Name of transferor pharmacist.

3. Both the original and transferred prescription must be maintained for a period of two years from the date of the last refill.

4. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

5. The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

8:65-7.15 Partial filling of prescriptions; schedules III and IV

(a) The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible, provided that:

1. Each partial filling is recorded in the same manner as a refilling;

2. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

3. No dispensing occurs after six months after the date on which the prescription was issued.

8:65-7.16 Labeling of substances; schedules III and IV

(a) The partial filling of a prescription for a controlled substance listed in schedule III or IV shall affix to the package a label conforming to the provisions set forth in N.J.S.A. 24:21-17.

(b) The requirements of subsection (a) of this section do not apply when a controlled substance listed in schedule III or IV is prescribed for administration to an ultimate user who is institutionalized: provided, that:

1. Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in schedule III or IV is dispensed at one time;

2. The controlled substance listed in schedule III or IV is not in the possession of the ultimate user prior to administration;

3. The institution maintains appropriate safeguards and records the proper administration, control, dispensing and storage of the controlled substance listed in schedule III or IV; and

4. The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

8:65-7.17 Filing prescriptions; schedules III and IV

All prescriptions for controlled substances listed in schedules III and IV shall be kept in accordance with N.J.A.C. 8:65-5.17.

8:65-7.18 Requirement of prescriptions; schedule V

(a) A pharmacist may dispense directly a controlled substance listed in schedule V pursuant to a prescription as required for controlled substances listed in N.J.A.C. 8:65-7.13 schedules III and IV. A prescription for a controlled substance listed in schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with N.J.A.C. 8:65-7.16 and file the prescription in accordance with N.J.A.C. 8:65-7.17.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule V in the course of his professional practice without a prescription, subject to N.J.A.C. 8:65-7.7.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in N.J.A.C. 8:65-5.4(b) except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner, which is dispensed for immediate administration to the ultimate user, subject to N.J.A.C. 8:65-7.7.

(d) The transfer of original prescription information for a controlled dangerous substance listed in schedule V for the purpose of refill dispensing is permissible between pharmacies on a one time basis subject to the following requirements:

1. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

   i. Write the word ‘‘VOID’’ on the face of the invalidated prescription;

   ii. Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information;

   iii. Record the date of the transfer and the name of the pharmacist transferring the information.

2. The pharmacist receiving the transferred prescription information shall reduce to writing the following:

   i. Write the word ‘‘TRANSFER’’ on the face the prescription;

   ii. Provide all information required to be on a prescription pursuant to N.J.S.A. 24:21-17 and include:

(1) Date of issuance of original prescription;

(2) Original number of refills authorized on original prescription;

(3) Date of original dispensing;

(4) Number of valid refills remaining and date of last refill;

(5) Pharmacy's name, address and DEA registration number and original number from which the prescription information was transferred;

(6) Name of transferor pharmacist.

3. Both the original and transferred prescription must be maintained for a period of two years from the date of the last refill.

4. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

5. The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

8:65-7.19 Dispensing without prescription

(a) A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist (as defined in 8:65-7.1), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

2. Not more than 240 cc. (eight ounces) of any such controlled substance containing opium, nor more than 120 cc. (four ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

3. The purchaser is at least 18 years of age;

4. The pharmacist requires every purchaser of a controlled substance under this Section not known to him to furnish suitable identification (including proof of age where appropriate);

5. A bound record book for dispensing of controlled substances under this Section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of N.J.A.C. 8:65-5.4); and

(b) A prescription is not required for distribution or dispensing of the substance pursuant to another Federal, State or local law.

SUBCHAPTER 8. MISCELLANEOUS PROVISIONS

8:65-8.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Act'' means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951). Any term not defined in this Section shall have the definition set forth in Sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in 301.02.

8:65-8.2 Application of State Law and other Federal Law

Nothing in Parts 301 through 308, 311, 312, 316 of Federal Regulations shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

8:65-8.3 Exceptions to regulations

(a) Any person may apply for an exception to the application of any provision of Parts 301 through 308, 311, 312 of Federal Regulations by filing a written request stating the reasons for such exception.

(b) Requests shall be filed with the Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C. 20537.

(c) The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

8:65-8.4 Distribution by dispenser to another practitioner

(a) A practitioner who is registered to dispense controlled substances may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or its patients; provided, that:

1. The practitioner to whom the controlled substance is to be distributed is registered under the Act and the State Act (N.J.S.A. 24:21-10) to dispense that controlled substance;

2. The distribution of such controlled substance is recorded by the distributing practitioner in accordance with N.J.A.C. 8:65-5.17(a)5 and by the receiving practitioner in accordance with N.J.A.C. 8:65-5.17(a)3;

3. If the substance is listed in schedule I or II, an order form is used as required in N.J.A.C. 8:65-6;

4. The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the 12-month period in which the practitioner is registered to dispense does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the 12-month period.

(b) If, at any time during the 12-month period which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section will exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by him during the 12-month period, the practitioner shall obtain a registration to distribute controlled substances.

8:65-8.5 Manufacture and distribution of narcotic solutions and compounds by a pharmacist

As an incident to a distribution under N.J.A.C. 8:65-8.4 a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the completed solution, compound or mixture.

8:65-8.6 Distribution to supplier

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer.

(b) In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of the Act and N.J.A.C. 8:65-6 and be maintained as the written record of the transaction. Any person not required to register pursuant to Section 302(c) or 1007(b)1 of the Act or N.J.A.C. 8:65-1.3 shall be exempt from maintaining the records required by this section.

8:65-8.7 Distribution upon discontinuance or transfer of business

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Federal Certificate of Registration, and any unexecuted order forms in his possession to the Drug Control Unit as well as the State Certificate of Registration for cancellation. Any controlled substances in his possession may be disposed of in accordance with Section 307.21 of the Act or N.J.A.C. 8:65-8.10 or by transfer to another registrant. If the registrant desires to transfer the substances to another registrant, he shall take an inventory, together with his name, address, and registration number, and the name, address, and registration number of the proposed transferee and send them to the Special Agent in Charge of the District Office of the Drug Enforcement Administration in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Special Agent in Charge does not notify the registrant that the transfer should be postponed or cancelled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in schedule I or II must be transferred pursuant to an order form in accordance with Part 305 of the Act or N.J.A.C. 8:65-6. Schedule III, IV and V substances will be transferred in accordance to the inventory prepared by the registrant and submitted to the Special Agent in Charge. If the Special Agent in Charge denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substances in accordance with N.J.A.C. 8:65-8.10 or transfer the substances to another registrant in accordance with this section and/or instructions of the Special Agent in Charge.

(b) In the case of registrants required to make reports pursuant to Part 304 of the Act, a report marked ''Final'' will be prepared and submitted by the transferor registrant showing the disposition of all the controlled substances for which a report is required; no additional reports will be required from him, provided that no further transactions involving controlled substances are consummated by him. The initial report of the transferee registrant shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor registrant, and the substances transferred to him shall be reported as receipts in his initial report.

(c) A registrant shall notify the Drug Control Unit in writing no less than 15 days prior to the discontinuance or transfer of business activities with respect to controlled substances as set forth in (a) above, unless the Program waives requirements in individual instances. Such notification shall include but not be limited to:

1. Name, address, State CDS and Federal DEA registration numbers of the registrant discontinuing or transferring his controlled substances activities;
2. Name, address, State CDS and Federal DEA registration numbers of the registrant, or proof of application for same, of registrant to whom the controlled substances are to be transferred;
3. Name, address, State CDS and Federal DEA registration numbers,or proof of application for same of the registrant receiving the records, which include prescription files, or patient orders of practitioners of the discontinued business;
4. Name, and address of the person or firm who will maintain records, such as invoices, purchase records and executed order forms of the discontinued or transferred business for a period of not less than two years; and
5. The date on which the discontinuance or transfer of the business activity will take place.

8:65-8.8 Distribution to ocean vessels or aircraft

(a) Any registrant lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to a medical officer, master or first officer, of any ocean vessel engaged in international trade or in trade between points of the United States and any merchant vessel belonging to the United States Government; or to any aircraft operated by a carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301) provided that:

1. The medical officer shall be:

i. Licensed in a state as a physician;

ii. Employed by the owner or operator of the vessel, aircraft or other entity; and

iii. Registered under the Act at either of the following locations:

(1) The principal office of the owner or operator of the vessel, aircraft or other entity; or (2) At any other location provided that the name, address, registration number and expiration date as they appear on the Certificate of Registration for this location are maintained for inspection at said principal office in a readily retrievable manner.

2. A registered medical officer may serve as medical officer for more than one vessel, aircraft, or other entity under a single registration, unless he serves as medical officer for more than one owner or operator, in which case he shall either maintain a separate registration at the location of the principal office of each such owner or operator or utilize one or more registrations pursuant to 1iii(2) above.
3. If no medical officer is employed by the owner or operator of a vessel or aircraft, or in the event the medical officer is not accessible and the acquisition of controlled substance is required, the master or first officer of the vessel, or aircraft, who shall not be registered, may purchase controlled substances from a registered manufacturer or distributor or from an authorized pharmacy through the following procedure:

i. The master or first officer of the vessel or aircraft must personally appear at the vendor's place of business, present proper identification, (for example, Seaman's photographic identification card) and a written requisition for the controlled substances;

ii. The written requisition must be on the vessel or aircraft's official stationery or purchase order and must include the name and address of the vendor, the name of the controlled substance (dosage form, strength and number or volume per container) number of containers ordered, the name of the vessel, the vessel's official number and country of registry, the owner or operator of the vessel, the port at which the vessel is located, the controlled substances and the date of the requisition;

iii. The vendor may, after verifying the identification of the vessel's officer requisitioning the controlled substances, deliver the controlled substances to that officer. The transaction shall be documented, in triplicate, on a record of sale in a format similar to that outlined in this subsection. The vessel's requisition shall be attached to copy 1 of the record of sale and filed with the controlled substances records of the vendor. Copy 2 of the record of sale shall be furnished to the officer of the vessel and retained aboard the vessel. Copy 3 of the record of sale shall be forwarded to the nearest DEA Division office within 15 days after the end of the month in which the sale is made;

iv. The vendor's record of sale should be similar to, and must contain all the information required in the following format:

Sale of Controlled Substances to Vessels

(Name of Registrant) _____

(Address of Registrant) _____

(DEA Registration Number) _____

Line No.	Number of Packages	Size of Packages	Name	Pkg. Dist.	Date
1.					
2.					
3.					

Line numbers may be continued according to the needs of the vendor.

Number of lines completed _____

Name of the vessel _____

Vessel's official number _____

Vessel's country of registry _____

Owner or operator of vessel _____

Name and title of vessel's officer who presented requisition _____

Signature of vessel's officer who presented the requisition _____

4. Any registered pharmacy which wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided that:

i. The registered pharmacy notifies the nearest Division officer of the Drug Enforcement Administration of its intentions to distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address and

registration number of the pharmacy as well as the date upon which such activity will commence; and

ii. Such activity is authorized by state law; and

iii. The total number of dosage units of controlled substances meet the requirements of N.J.A.C. 8:65-8.4.

8:65-8.9 Incidental manufacture of controlled substances

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacturer of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to Part 303 of the Act (if such substance or class is listed in schedule I or II) shall be exempt from the requirement of registration pursuant to Part 301 of the Act and, if such incidentally manufactured substance is listed in schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to Part 303 of the Act, if such substances are disposed of in accordance with Part 307.21 of the Act.

8:65-8.10 Procedure for disposing of controlled substances

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 80 Mulberry St., 2nd Floor, Newark, N.J. 07102 for authority and instructions to dispose of such substance. The person may also contact the Drug Control Unit for such authority and instruction. The request shall be made in the following manner:

1. If the person is a registrant required to make reports pursuant to Part 304 of the Act, he shall list the controlled substances or substance which he desires to dispose of on the ''b'' subpart of the report normally filed by him, and submit three copies of that report to the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 80 Mulberry St., 2nd Floor, Newark, N.J. 07102.

2. If the person is a registrant not required to make reports pursuant to Part 304 of the Act, he shall list the controlled substance or substances which he wishes to dispose of on DEA-41 form or Form DDC-51 of the Drug Control Unit. If he elects to use the DEA-41 form, he must submit three copies of that form to the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 80 Mulberry St., 2nd Floor, Newark, N.J. 07102. If the person elects to use the DDC-51 form, he must submit three copies of that form to the Drug Control Unit or may telephone that agency.

3. If the person is not a registrant he shall submit to the Special Agent in Charge a letter stating:

i. The name and address of the person;

ii. The name and quantity of each controlled substance to be disposed of;

iii. How the applicant obtained the substance, if known; and

iv. The name, address and registration number, if known, of the person who possessed the controlled substance prior to the applicant, if known.

(b) The Special Agent in Charge or the Drug Control Unit shall authorize and instruct the applicant to dispose of the controlled substances in one of the following manners:

1. By transfer to the District Office of the Special Agent in Charge;

2. By transfer to a person registered under the act and authorized to possess such substance or substances;

3. By destruction in the presence of an agent of the District Office of the Special Agent in Charge or an agent of the Drug Control Unit; or

4. By such other means as the Special Agent in Charge or the Drug Control Unit may determine to assure that the substance or substances does not become available to unauthorized persons.

(c) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any state.

8:65-8.11 Disposal of controlled substances by the District Office

(a) Any controlled substance delivered to the District Office of the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration under 307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, U.S. Department of Justice, Drug Enforcement Administration, Washington, D.C. 20537.

(b) The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended.

(c) The delivery of such controlled drugs shall be ordered by the Special Agent in Charge, if in his opinion, there exists a medical or scientific need therefor.

8:65-8.12 Native American Church

The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the American Native Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

8:65-8.13 Humane societies and animal care facilities

(a) Incorporated humane societies or licensed animal care facilities authorized to purchase, possess and to dispense Sodium Pentobarbital for animal euthanasia pursuant to N.J.S.A. 24:21-11(f) shall:

1. Be authorized to dispense any commercially prepared Sodium Pentobarbital drug product for animal euthanasia approved for interstate sale by the United States Food and Drug Administration, provided the registrant complies with the approved recommended dosage regime in the labeling;

2. Be authorized to dispense a standard compounded formula of Sodium Pentobarbital for animal euthanasia established by the Department as follows:

   i. Sodium Pentobarbital injection (for animal euthanasia), formula non-sterile solution: U.S.P. Pentobarbital Sodium (Powder) 460 grams Isopropyl Alcohol 250 mls. Methyl Violet 1 drop U.S.P. Water for injection Quantity sufficient to make 1000 mls.

   ii. Using the formula in (a)2 above, the strength of this mixture will provide 460 mgs of Pentobarbital Sodium per milliliter.

   iii. Lethal dose: one milliliter per 10 pounds of body weight for small animals; horses and other

large animals-one milliliter per 10 pounds of body weight subject to a maximum dose of 100 milliliters.

iv. Package and storage: Package in tight containers with rubber stoppers and store under refrigeration. Solutions decompose on standing. Heat accelerates the decomposition.

v. Expiration date: five days from date or manufacture.

(b) Labeling: sample labeling is as follows:

1.
2.
3.
4.
5. 7.
6. 8.
9.

1. Name and address, city and State of registrant;
2. Name of preparation: ''Pentobarbital Sodium Injection ..... '';
3. Strength of the preparation: ''460 milligrams per one milliliter ..... '';
4. ''Lethal dose: one milliliter per 10 pounds of body weight for small animals; horses and large animals-one milliliter per 10 pounds of body weight subject to a maximum dose of 100 milliliters'';
5. ''Batch number ..... '';
6. ''Net contents ..... '';
7. ''Expiration date ..... '';
8. ''Keep under refrigeration.'';
9. ''Warning: Do not use the injection if it contains a precipitate.''

(c) A master formula and production record shall be made and retained on file at the formulating (compounding) site. This record shall contain:

1. Name, address, city and State of registrant;
2. Name and strength of the product and a description of the dosage form;
3. The name and weight or measure of each active ingredient including the control number of each such ingredient;
4. A statement of the theoretical yield of finished product;
5. A statement describing the equipment and utensils used in the formulating (compounding);
6. A description of the finished drug product containers and closures including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling; and
7. Complete manufacturing and control instructions, procedures, special notations and precautions to be followed.

(d) Batch production records shall be prepared for each batch of drug product produced and shall include complete information relating to the production of each batch. The records shall contain:

1. An accurate reproduction of the appropriate master formula production record, checked for accuracy, dated and signed;
2. Documentation that each significant step in the manufacture, processing, packaging or holding of the batch was accomplished, including:
   i. Dates;
   ii. Identity of the individual equipment used;
   iii. Specific identification of each batch of component or materials used;
   iv. Weights and/or measures of components used in processing;
   v. Copy of all labeling used;
   vi. Identification of the person performing each step in the process and identification of the person checking the weights, measures and operations;
   vii. A statement of the theoretical yield; and
   viii. A statement of the actual yield.

SUBCHAPTER 9. (RESERVED)

SUBCHAPTER 10. CONTROLLED DANGEROUS SUBSTANCES SCHEDULES

8:65-10.1 Controlled dangerous substances; Schedule I

(a) The following are criteria for inclusion in Schedule I of controlled dangerous substances.

1. The drug or other substance has high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. There is lack of accepted safety for use of the drug or other substance under medical supervision.

(b) The following is Schedule I listing of the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substance code number.

1. Opiates: Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Acetylmethadol	9603
(except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, LAAM)	
Allylprodine	9602
Alpha Methylfentanyl	9614
Alphacetylmethadol	9603
Alphameprodine	9604

Alphamethadol	9605
Benzethidine	9606
Betacetylmethadol	9607
Betameprodine	9608
Betamethadol	9609
Betaprodine	9611
Clonitazene	9612
Dextromeramide	9613
Diampromide	9615
Diethylthiambutene	9616
Difenoxin	9168
Dimenoxadol	9617
Dimepheptanol	9618
Dimethylthiambutene	9619
Dioxaphetylbutyrate	9621
Dipipanone	9622
Ethylmethylthiambutene	9623
Etonitazene	9624
Etoxeridine	9625
Furethidine	9626
Hydroxypethidine	9627
Ketobemidone	9628
Levomoramide	9629
Levophenacylmorphan	9631
Morpheridine	9632
Noracymethadol	9633
Norlevorphanol	9634
Normethodone	9635
Norpipanone	9636
Phenadoxone	9637
Phenampromide	9638
Phenomorphan	9647
Phenoperidine	9641
Piritramide	9642
Proheptazine	9643
Properidine	9644
Propiram	9649
Racemoramide	9645
Tilidine	9750
Trimeperidine	9646

2. Opium derivatives: Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Acetorphine	9319
Acetyldihydrocodeine (Acetylcodone)	9051
Benzylmorphine	9052

Codeine methylbromide	9070
Codeine-N-Oxide	9053
Cyprenorphine	9054
Desomorphine	9055
Dihydromorphone	9145
Drotebanol	9335
Etorphine (Except Hydrochloride Salt)	9056
Heroin	9200
Hydromorphinol	9301
Methyldesorphine	9302
Methyldihydromorphine	9404
Morphine Methylbromide	9305
Morphine Methylsulfonate	9306
Morphine-N-Oxide	9307
Myrephine	9308
Nicocodeine	9309
Nicomorphine	9312
Normorphine	9313
Pholcodine	9314
Thebacon	9315

3. Hallucinogenic substances: Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term ''isomer'' includes the optical, positions, and geometric isomers) (listed by generic/established or chemical name with CDS code):

4-bromo-2,5-dimethoxy-amphetamine (Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA.)	7391
2,5-dimethoxyamphetamine (Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.)	7396
4-methoxyamphetamine (Some trade or other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyamphetamine, PMA.)	7411
5-methoxy-3,4-methylenedioxy-amphetamine.	7401
4-methyl-2,5-dimethoxy-amphetamine (Some trade and other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; ''DOM''; and ''STP''.)	7395
3,4-methylenedioxy amphetamine.	7400
3,4,5-trimethoxy amphetamine	7390
Beta-hydroxy-3-methylfentanyl	9830
Bufoteine (Some trade and other names: 3-(beta-Dimethyl-aminoethyl-5-hydroxyindole; 3-(2-dimethylaminoethyl-5-indolol;N,N-dimethylsero-tonin; 5-hydroxy-N,N-dimethyltryptamine; mappine.)	7395
Diethyltryptamine (Some trade and other names: N, N-Diethyltryptamine DET.)	7395
Dimethyltryptamine (Some trade or other names: DMT.)	7435

Ibogaine (Some trade and other names: 7-Ethyl-6,6,7,8,9,10,12, 13-octahydro-2-methosy-6,9-methano-5H-pyrido (1',2':1,2 axepino 5,6-b) Indole; tabernanthe iboga.) 7260

Lysergic acid diethylamide 7315

Marihuana 7360

Mescaline 7381

4-methylaminorex 1590

Methylenedioxymethamphetamine 7405

3,4-methylenedioxy-N-ethylamphetamine 7404

Parahexyl (Some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetra-hydro-6,6,9-trimethyl-6H-dibe nzyo (b,d) pyran; Synhexyl.) 7374

Peyote (Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture or preparation of such plant, its seeds or extracts.) 7415

N-ethyl-3-piperidyl benzilate 7482

N-hydroxy-3-4-methylenedioxyamphetamine 7402

N-methyl-3-piperidyl benzilate 7484

Psilocybin 7437

Psilocyn 7438

Tetrahydrocannabinols (Synthetic equivalents of the substances contained in the plant, or in the resinous extractives cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
1 cis or trans tetrahydrocannabinol, and their optical isomers. 6 cis or trans tetrahydrocannabinol, and their optical isomers. 3,4 cis or trans tetrahydrocannabinol, and its optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.) 7370

Thiphene Analog of Phencyclidine (Some trade or other names: 1-1-(2-theinyl) cyclohexyl piperidine; 2-Thienyl Analog of Phencyclidine; TPCP.) 7470

1-[1-(2-thienyl)cycloheryl] pyrolidine 7473

4. Depressants: Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

   i. Mecloqualone 2572

   ii. Methaqualone 2565

5. Precursors (listed with CDS code):

N-Ethyl-1-phenylcyclohexylamine 7455

1-(1-phenylcyclohexyl) pyrrolidine 7458

6. Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

Fenethylline 1503
n-Ethylamphetamine 1475

7. Temporary listing of substances subject to emergency scheduling. Any material, compound, mixture, or preparation which contains any quantity of the following substances:

i. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-iperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers 9613.

ii. 3, 4-Methylenedioxymethamphetamine: its optical positional and geometric isomers, salts and salts of isomers. 7405

iii. 1-methyl-4-phenyl-4-proprionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers 9661

iv. 1-2(2-phenylethyl)-4-4phenyl-4-acetyloxypipidine (PEPAP), it optical isomers, salts and salts of isomers 9663.

v. acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenyl) ethyl-4-piperidyl)-N-phenylacetamide), its optical isomers, salts, and salts of isomers 9615

vi. alpha-methylthiofentanyl (N-(1-(1-methyl-2-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide), its optical isomers, salts, and salts of isomers 9832

vii. benzylfentanyl (N-(1-benzyl-4-piperidyl)-N-phenylpropanamide),

its optical isomers, salts, and salts of isomers 9818

viii. beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl)-N-phenylpropanamide), its isomers, salts, and salts of isomers 9830

ix. beta-hydroxy-3-methylfentanyl (N-(3-methyl-1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl)-N-phenylpropanamide), its isomers, salts, and salts of isomers 9831

x. 3-methylthiofentanyl (N-(3-methyl-1-(2-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide, its isomers, salts, and salts of isomers 9833

xi. thenylfentanyl (N-(1-(2-(2-thienyl) methyl-4-piperidyl)-N-phenylpropanamide, its isomers, salts, and salts of isomers 9834

xii. thiofentanyl (N-(1-(2-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide, its isomers, salts, and salts of isomers 9835.

xiii. Paraflourofentanyl (N-(2-1-phenylethyl)-4-piperidyl)-N-(4-flourophenyl) propanamide.

xiv. Methcathinone (2-Methylamino-1-Phenylpropran-1-one; Ephedrone; Monomethylpropion; UR 1431), its salts, optical isomers and salts of its isomers. 1237.

8:65-10.2 Controlled dangerous substances; Schedule II

(a) The following are criteria for inclusion in Schedule II of controlled dangerous substances.

1. The drug or other substance has a high potential for abuse.

2. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

3. Abuse of the drug or other substance may lead to severe psychological or physical dependence.

(b) The following is Schedule II listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substance code number.

1. Substances, vegetable origin or chemical synthesis: Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

i. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrophan, nalbuphine, nalmefene, maloxone and naltrexone, and their respective salts, but including the following (listed by generic/established or chemical name with CDS code):

Raw opium	9600
Opium extracts	9610
Opium fluid extracts	9620
Powdered opium	9639
Granulated opium	9640
Tincture of opium	9630
Codeine	9050
Ethylmorphine	9190
Etorphine HCL	9059
Hydrocodone	9133
Hydromorphone	9194
Metopon	9620
Morphine	9300
Oxycodone	9143
Oxymorphone	9652
Thebaine	9333

ii. Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (i) of this paragraph except that these substances shall not include the isoquinoline akaloids of opium.

iii. Opium poppy and poppy straw (CDS code 9650).

iv. Coca leaves (CDS code 9040) and any salt, compounds, derivative, or preparation of coca leaves, and any salt, compounds, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (CDS code 9041) or ecgonine (CDS code 9180).

v. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy) (CDS code 9670).

2. Opiates: Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical

designation, dextorphan and levopropoxyphene excepted, (listed by generic/established or chemical name with CDS code):

Alfentanil	9737
Alphaprodine	9010
Anileridine	9020
Bezitramide	9800
Carfentanil	9743
Dihydrocodeine	9120
Diphenoxylate	9170
Fentanyl	9801
Isomethadone	9226
Levo-alphacetylmethadol (Some other names: levo-alpha-acetyl-methadol, levomethadyl acetate, LAAM)	9648
Levomethorphan	9210
Levorphanol	9220
Metazocine	9240
Methadone	9250
Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane	9254
Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid	9802
Pethidine	9230
Pethidine-Intermediate-A, 4-cyano-1-methyl-4-Phenylpiperidine	9232
Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic Acid	9234
Phenazocine	9715
Piminodine	9730
Racemethorphan	9732
Racemorphan	9733
Sufentanil	9740

3. Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

Amphetamine, its salts, optical isomers and salts of its optical isomers	1100
Methamphetamine, its salts, isomers and salts of its isomers	1105
Phenmetrazine and its salt	1630
Methylphenidate	1726

4. Depressants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Amobarbital	2125
Glutethimide	2550
Pentobarbital	2270
Phencyclidine	7471
Secobarbital	2315

5. Immediate precursors: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

i. Immediate precursor to amphetamine and methamphetamine:

(1) Phenylacetone-(Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone) (CDS code 8501).

ii. Immediate precursor to phencyclidine (PCP):

(1) 1-phenylcycloheylamine, (CDS code 7460);

(2) 1-piperidinocyclohexane-carbonitrile (PCC)6 (CDS code 8603).

6. Bulk chemical: Bulk dextropropoxyphene (non-dosage forms).

7. Hallucinogenic substances:

i. Dronabinol (synthetic) in sesame oil encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration Approved product 7369.

ii. Some other names for Dronabinol: (6aR-trans)-6a-7, 8, 10a-tetrahydro-6, 6,9-trimethyl-3-pentyl-6H-dibenzyl (b,d) pyran-1-01, or (w)-delta-9-(trans)-tetra-hydrocannabinol.

iii. Nabilone 7379

(another name for Nabilone: (v)-trans-3-(1, 1-dimethylheptyl)-6, 6a, 7, 8, 10a-hexahydro-1-hydroxy-6, 6-dimenthyl-9H-dibenzo(b, d)pyran-9-one).

8:65-10.3 Controlled dangerous substances; Schedule III

(a) The following are criteria for inclusion in Schedule III of controlled dangerous substances.

1. The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.

2. The drug or other substance has a currently accepted medical use in the United States.

3. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(b) The following is Schedule III listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers:

1. Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

i. Those compounds, mixtures, or preparation in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on

August 25, 1971, as excepted compounds under 21 CFR 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances (1405).

ii. The following CDS code (listed by generic/established or chemical name with CDS code):

Benzphetamine	1228
Chlorphentermine	1645
Clortermine	1647
Phendimetrazine	1615

2. Depressants: Unless specifically excepted or unless listed in another Schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system.

i. Any compound, mixture or preparation containing (listed by generic/established or chemical name with CDS code):

Amobarbital	2126
Secobarbital	2316
Pentobarbital	2271

or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

ii. Any suppository dosage form containing (listed by generic/established or chemical name with CDS code):

Amobarbital	2126
Secobarbital	2316
Pentobarbital	2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

iii. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof (C.D.S. 2100).

iv. The following (listed by generic/established or chemical name with CDS code):

Chlorhexadol	2510
Lysergic acid	7300
Lysergic acid amide	7310
Methyprylon	2575
Sulfondiethylmethane	2600
Sulfonethylmethane	2605
Sulfonmethane	2610
Nalorphine	9400

v. Tiletamine and zolazepam or any salt thereof 7295

(1) Some trade or other names for a tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)- 6, 8-dihydro-1, 3, 8-trimethylpyrazolo[3,4,3] [1,4] diazepin-(1H)-one. Flupyrazapon.

3. Narcotic drugs: Unless specifically excepted or unless listed in another schedule, any material, compound mixture, or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

i. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium (CDS code 9803).

ii. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9804).

iii. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium (CDS code 9805).

iv. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9806).

v. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9807) or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9808).

vi. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9809).

vii. Not more than 50 milligrams of morphine per 100 milliliters per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS 9810).

4. Anabolic steroids (CDS Code 4000), with the exception of those anabolic steroid products specified in (b)5 below, as follows:

i. Boldenone;

ii. Chlorotestosterone (4-chlorotestosterone);

iii. Clostebol;

iv. Dehydrochlormethyltestosterone;

v. Dihydrotestosterone (4-dihydrotesterone);

vi. Drostanolone;

vii. Ethylestrenol;

viii. Fluoxymesterone;

ix. Formebulone (formebolone);

x. Mesterolone;

xi. Methandienone;

xii. Methandranone;

xiii. Methandriol;

xiv. Methandrostenolone;

xv. Methenolone;

xvi. Methyltestosterone;

xvii. Mibolerone;

xviii. Nandrolone;

xix. Norethandrolone;

xx. Oxandrolone;

xxi. Oxymesterone;

xxii. Oxymetholone;

xxiii. Stanolone;

xxiv. Stanozolol;

xxv. Testolactone;

xxvi. Testosterone;

xxvii. Trenbolone; and

xxviii. Any salt, ester, or isomer of a drug or substance described or listed above, if that salt, ester, or isomer promotes muscle growth.

5. Table of Exempt Anabolic Steriod products:

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Androgyn L.A. St.Louis,MO	Forest Pharmaceuticals	0456-1005	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Andro-Estro 90-4	Rugby Laboratories, Rockville Centre, NY	0536-1605	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456-1020	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DEPO-T.E.	Quality Research Pharm, Carmel, IN	52765-257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
depTESTROGEN	Martica Pharmaceuticals, Phoenix AZ	51698-257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml ,

Duomone	Wintec Pharmaceutical, Pacific, MO	52047-360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
DURATESTRIN	W.E. Hauck, Alpharetta, GA	43797-016	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684-0102	Vial	Testosterone cypionate Esterified	50 mg/ml
Estratest	Solvay Pharmaceuticals, Marietta,GA	0032-1026	TB	Esterified estrogens Methyltestosterone	1.25 mg 2.5 mg
Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032-1023	TB	Esterified estrogens Methyltestosterone	0.625 mg 1.25 mg
PAN ESTRA TEST	Pan American Labs, Covington, LA	0525-0175	Vial	Testosterone cypionate Estradiol cypionate	50 /ml 2 mg/ml
Premann with Methyltestoster-	Ayerst Labs Inc., New York, NY	0046-0879	TB	Conjugated estrogens Methyltestosterone	1.25mg 10.0 mg one
Premann with Methyltestoster-One	Ayerst Labs Inc.,New York, NY	0046-0878	TB	Conjugated estrogens Methyltestosterone	0.625 mg 5.0 mg
Synovex H Pellets In process	Syntex Animal Health, Palo Alto, CA		Drum	Testosterone propionate Estradiol benzoate	25 mg 2.5 mg
Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA		Drum	Testosterone propionate Estradiol	10 parts 1 part benzoate
TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536-9470	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testagen	Clint Pharmaceuticals, Nashville, TN	55553-257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone CYP 50 Estradiol Cyp	I.D.E.-Interstate Amityville, NY	0814-7737	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml2 mg/ml
Testosterone Cy Pionate-Estra Diol Cypionate Injection	Best Generics No. Miami Beach, Fl	54274-530	Vial	Testosterone cy pionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cy 2Pionate-Estra Diol Cypionate injection	Goldine Labs, Ft. Lauderdale, FL	0182-3069	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml mg/ml

Testosterone Cy Pionate-Estra Diol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6611	Vial	Testosterone cy pionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cy Pionate-Estra Diol Cypionate Injection	Steris Labs, Inc. Phoenix, AZ	0402-0257	Vial	Testosterone cy pionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cy Pionate-Estra Diol Cypionate Injection	The Upjohn Co. Kalamazoo, MI	0009-0253	Vial	Testosterone cy pionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone En-Anthate-Estra Diol Valerate Injection	Goldine Labs, Ft. Lauderdale, FL	0182-3073	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone En-Anthate-Estra Diol Valerate In-Jection	Schein Pharma-Lauderdale, FL	0364-6618	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone En-Anthate-Estra Diol Valerate In-Jection	Steris Labs, Inc. . Phoenix, AZ	0402-0360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Tilapia Sex Reversal Feed (In vestigatonal)	Zeigler Brothers, Inc. Gardners,	Plastic Bags		Methyltestosterone fish feed	60 mg/1 kg

8:65-10.4 Controlled dangerous substances; schedule IV

(a) The following are criteria for inclusion in schedule IV of controlled dangerous substance.

1. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
2. The drug or other substance has a currently accepted medical use in treatment in the United States.
3. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

(b) The following is Schedule IV listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers.

1. Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Cathine	1230
Diethylpropion	1608
Fencamfamin	1760
Fenfluramine	1670
Fenproporex	1575
Mazindol	1650
Mefenorex	1580
Phentermine	1640
Pemoline (including organometallic complexes and chelates thereof)	1530

2. Depressants: Unless specifically specified excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Alphazolam	2862
Barbital	2145
Bromazepam	2748
Camazepam	2749
Chloral betaine	2460
Chloral hydrate	2465
Chlordiazepoxide (except Librax and Menrium)	2744
Clobazam	2751
Clonazepam	2737
Clorazepate	2768
Clotiazepam	2752
Cloxazolam	2753
Delorazepam	2754
Diazepam	2765
Estazolam	2756
Ethchlorvynol	2540
Ethinamate	2545
Ethyl loflazepate	2758
Fludiazepam	2759
Flunitrazepam	2763
Flurazepam	2767
Halazepam	2762
Haloxazolam	2771
Ketazolam	2772
Loprazolam	2773
Lorazepam	2885
Lormetazepam	2774
Mebutamate	2800
Medazepam	2836
Meprobamate	2820
Methohexital	2264
Methylphenobarbital (methobarbital)	2250
Midazolam	2884

Nimetazepam	2837
Nitrazepam	2834
Nordiazepam	2838
Oxazepam	2835
Oxzapolam	2839
Paraldehyde	2585
Petrichloral	2591
Phenobarbital	2285
Pimazepam	2883
Prazepam	2764
Quazepam	2881
Temazepam	2925
Tetrazepam	2886
Triazolam	2887

3. Other substances: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts (listed by generic/established or chemical name with CDS code):

Pentazocine	9709

4. Narcotic drugs: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

i. Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit, CDS Code 9167.

ii. Dextropropoxyphene (alpha-(v)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane), CDS Code 9278.

8:65-10.5 Controlled dangerous substances; Schedule V

(a) The following are criteria for inclusion in Schedule V of controlled dangerous substances.

1. The substance has a low potential for abuse relative to the substances listed in Schedule IV.

2. The substance has currently accepted medical use in treatment in the United States.

3. The substance has limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV.

(b) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, or mixture or preparation containing any of the following narcotic drugs and their salts is included in this schedule:

Buprenorphine	9064

(c) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Narcotic Drugs Containing Non-Narcotic Active Medicinal Ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid in limited quantities as set forth below, which shall include one or more non-narcotic

active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone, is included in this schedule:

1. Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams.
2. Not more than 100 milligrams of dihydrocodeine or any of its salts per 100 milliliters or per 100 grams.
3. Not more than 100 milligrams of ethylmorphine or any of its salts per 100 milliliters or per 100 grams.
4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
5. Not more than 100 milligrams of opium or any of its salts per 100 milliliters or per 100 grams.
6. Difenoxin, 0.5 mg. in combination with 0.025 mg. atropine sulfate.

(d) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Stimulants. Unless specifically exempted or excluded, or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including salts, isomers and salts of isomers is included in this schedule:

Pyrovalerone 1485

8:65-10.6 Excluded O.T.C. substances

(a) The list of non-narcotic substances which, may, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301) may be lawfully sold over the counter without a prescription, are excluded from all schedules of the New Jersey Controlled Dangerous Substance Act.

(b) A complete list of non-narcotic substances is found in Section 1308.22 of 21 C.F.R. (38 F.R. 8255, March 30, 1973, as amended 41 F.R. 16553, April 20, 1976; 41 F.R. 53477, Dec. 7, 1976). Copies of 21 C.F.R., Part 1300 to end, revised as of April 1, 1977, may be purchased from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
Price-$4.25 per copy

(c) A complete listing of those non-narcotic substances subject to this subchapter may be reviewed in the office of the Drug Control Unit.

8:65-10.7 Excepted prescription drugs

(a) The list of drugs in dosage unit form, and any other drug of the quantitative composition listed for one of the listed drugs or which is the same except that it contains a lesser quantity of controlled substances, and which is restricted to dispensing by prescription, are excepted from the provisions of the New Jersey Controlled Dangerous Substances Act.

(b) A complete list of excepted prescription drugs are found in Section 1308.32 of 21 C.F.R. Copies of 21 C.F.R. Part 1300 to end, revised as of April 1, 1977, may be purchased from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20202
Price: $4.25 per copy

(c) A complete listing of those excepted prescription drugs subject to this subchapter may be reviewed in the office of the Drug Control Unit.

8:65-10.8 Exempt chemical preparations

A list of exempt preparations and mixtures as shown in 21 C.F.R. 1308.24, as amended by a final order published in the Federal Register on February 18, 1992 (see 57 F.R. 5818) which in the form and quantity listed in the application (indicated as the ''date of application'') are designatedexempt chemical preparations and are not subject to the provisions of the New Jersey Controlled Dangerous Substances Act.

SUBCHAPTER 11. NARCOTIC TREATMENT PROGRAM

8:65-11.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Compounder'' means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in

maintenance or detoxification treatment by another narcotic treatment program.

''Detoxification treatment'' means the administration or dispensing for a period not in excess of 21 days, of a narcotic drug or narcotic drugs in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time.

''Maintenance treatment'' means the dispensing for a period in excess of 21 days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

''Narcotic treatment program'' means a program engaged in maintenance or detoxification treatment with narcotic drugs.

8:65-11.2 Registration; fees

(a) Every person who engages in a narcotic treatment program, including a compounder, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration each year thereafter.

(b) In conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV and V, employees, agents, or affiliated practitioners in programs, need not register separately.

(c) Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to N.J.A.C. 8:65-5.6.

(d) For each registration or reregistration to engage in a narcotic treatment program, including a compounder, the applicant shall pay an annual fee of $20.00 at the time of application for registration or for renewal of registration.

(e) The payment of fees as required by subsection (d) of this Section shall be subject to the exemptions provided in N.J.A.C. 8:65-1.1.

8:65-11.3 Application forms

Application to conduct a narcotic treatment program, including a compounder, shall be made in accordance with the provisions of N.J.A.C. 8:65-1.4.

8:65-11.4 Security requirements

(a) Applicants to conduct a narcotic treatment program shall comply with the general security requirements as provided in N.J.A.C. 8:65-2.1.

(b) In addition to the security requirements required in (a) above, all manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

1. The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place hisspecific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

2. Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either the licensed practitioner or a registered nurse under direction of the licensed practitioner, a licensed practical nurse under the direction of the licensed practitioner, or a pharmacist under the direction of the licensed practitioner.

3. Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area.

4. All narcotic treatment programs must comply with the provisions of N.J.S.A. 26:2G-21 through 30; and with standards established by the Secretary of the Federal Department of Health and Human Services (after consultation with the Drug Enforcement Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

5. The Department may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security at a narcotic treatment program.

8:65-11.5 Persons required to keep records

(a) Applicants to conduct a narcotic treatment program shall comply with the provisions of N.J.S.A. 24:21-1 et seq. and the regulatory provisions of N.J.A.C. 8:65-8.4 to 8.8.

(b) In addition to the record keeping requirements required in subsection (a) of this Section, each person registered or authorized to maintain/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each controlled substance:

1. Name of substance;
2. Strength of substance;
3. Dosage form;
4. Date dispensed;
5. Adequate identification of patient (consumer);
6. Amount consumed;
7. Amount and dosage form taken home by patient;
8. Dispenser's initials.

(c) The records required by subsection (b) of this Section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with N.J.A.C. 8:65-5.4.

(d) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(e) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by Part 310 and Part 1401 of 21 U.S.C.

8:65-11.6 Records for treatment program which compound narcotics for treatment programs and other locations

(a) Each person registered or authorized to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

1. For each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other noncontrolled substances in finished form:

i. The name of the substance;

ii. The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

iii. The quantity received from other persons including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

iv. The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;

v. The quantity used to compound the same substance in finished form, including:

(1) The date and batch or other identifying number of each compounding;

(2) The quantity used in the compound;

(3) The finished form (for example, ten milligram tablets or ten milligram concentration per fluid ounce or milliliter);

(4) The number of units of finished form compounded;

(5) The quantity used in quality control;

(6) The quantity lost during compounding and the causes therefore, if known;

(7) The total quantity of the substances contained in the finished form;

(8) The theoretical and actual yields; and

(9) Such other information as is necessary to account for all controlled substances used in the compounding process.

vi. The quantity used to manufacture other controlled and noncontrolled substances; including the name of each substance manufactured and the information required in subparagraph v of this paragraph;

vii. The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

viii. The quantity exported directly by the registrant (under a registration as an exporter) including the date, quantity, and export permit or declaration number of each exportation; and

ix. The quantity disposed of by destruction, including the reason, date, and manner of destruction. All other destruction of narcotic controlled substances will comply with N.J.A.C. 8:65-8.9.

2. For each narcotic controlled substance in finished form:

i. The name of the substance;

ii. Each finished form (for example, ten-milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100-tablet bottle of three milliliter vial);

iii. The number of containers of each such commercial form compounded from bulk form by the registrant, including the information required pursuant to subparagraph v. of paragraph 1 of this Section;

iv. The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of person from whom the units were received;

v. The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or ization to import), including the date of, the number of units and/or commercial containers in, and the import or declaration number for, each importation;

vi. The number of units and/or commercial containers compoundedby the registrant from units in finished form received from others or imported, including:

(1) The date and batch or other identifying number of each compounding;

(2) The operation performed (for example, repackaging or relabeling);

(3) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and

(4) Such other information as is necessary to account for all substances used in the compounding process;

(5) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(6) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number of each exportation;

(7) The number of units finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with N.J.A.C. 8:65-8.9.

8:65-11.7 Drugs Used For Treatment of Narcotic Addicts

The FDA regulations at 21 C.F.R. 291, Drugs Used For Treatment of Narcotic Addicts, are incorporated herein by reference. All addiction treatment programs in New Jersey providing drugs used for treatment of narcotic addicts shall comply with these regulations and all the supplements and amendments thereto incorporated herein by reference.

CHAPTER 45C

UNIFORM REGULATIONS

SUBCHAPTER 1. LICENSEE DUTY TO COOPERATE AND TO COMPLY WITH BOARD ORDERS

13:45C-1.1 Applicability, scope and definitions

(a) This subchapter shall apply to all licensees of any board, committee or sub-unit within the Division of Consumer Affairs.

(b) For the purpose of this subchapter, ''licensee'' shall mean any licensee, permittee, certificate holder or registrant of:

1. The Division of Consumer Affairs;
2. Any professional or occupational licensing board within the Office of Professional/Occupational Boards and any committee, or other subunit of a board or committee located within the Division;
3. The Office of Consumer Protection; or
4. The Legalized Games of Chance Control Commission.

13:45C-1.2 Licensee's duty to cooperate in investigative inquiries

(a) A licensee shall cooperate in any inquiry, inspection or investigation conducted by, or on behalf of, a board, the Director or the licensee's licensing agency into a licensee's conduct, fitness or capacity to engage in a licensed profession or occupation where said inquiry is intended to evaluate such conduct, fitness or capacity for compliance with applicable statutory or regulatory provisions.

(b) A licensee's failure to cooperate, absent good cause or *bona fide* claim of a privilege not identified in N.J.A.C. 13:45C-1.5 as unavailable, may be deemed by the board, the Director, or the licensing agency to constitute professional or occupational misconduct within the meaning of N.J.S.A. 45:1-21(e) or the agency's enabling act and thus subject a licensee to disciplinary action pursuant to N.J.S.A. 45:1-21(h) or the agency's enabling act.

13:45C-1.3 Specific conduct deemed failure to cooperate

(a) The following conduct by a licensee may be deemed a failure to cooperate and, therefore, professional or occupational misconduct and grounds for suspension or revocation of licensure:

1. The failure to timely respond to an inquiry to provide information in response to a complaint received concerning licensee conduct;
2. The failure to timely provide records related to licensee conduct;
3. The failure to attend any scheduled proceeding at which the licensee's appearance is directed. In the event that a licensee elects to retain counsel for the purpose of representation in any such proceeding, it shall be the licensee's responsibility to do so in a timely fashion. The failure of a licensee to retain counsel, absent a showing of good cause therefor, shall not cause an adjournment of the proceeding;
4. The failure to timely respond or to provide information requested pursuant to a demand under N.J.S.A. 45:1-18 or other applicable law or to provide access to any premises from which a licensed profession or occupation is conducted. Included within this paragraph shall be the

failure to respond to any demand for statement or report under oath, the failure to permit the examination of any goods, ware or item used in the rendition of the professional or occupational service and the failure to grant access to records, books or other documents utilized in the practice of the occupation or profession;

5. The failure to answer any question pertinent to inquiry made pursuant to N.J.S.A. 45:1-18 or other applicable law unless the response to said question is subject to a bona fide claim of privilege;

6. The failure to make proper and timely response by way of appearance or production of documents to any subpoena issued pursuant to N.J.S.A. 45:1-18 or as may otherwise be provided by law; or

7. The failure to provide to the Board, the Director or the licensing agency timely notice of any change of address from that which appears on the licensee's most recent license renewal or application.

13:45C-1.4 Failure to comply with Board orders as professional or occupational misconduct

The failure of a licensee to comply with an order duly entered and served upon the licensee or of which the licensee has knowledge shall be deemed professional or occupational misconduct.

13:45C-1.5 Unavailability of privileges in investigative or disciplinary proceedings

(a) In any investigative inquiry conducted pursuant to N.J.S.A. 45:1-18 or in any disciplinary proceeding conducted pursuant to N.J.S.A. 45:1-21, or as may otherwise be authorized by law, the physician-patient privilege, psychologist-patient privilege, marriage and family therapist-client privilege, professional counselor-client privilege, associate counselor-client privilege, social worker-client privilege and the alcohol and drug counselor-client privilege shall be unavailable.

(b) Any statements or records otherwise subject to a claim of the stated privileges which may be obtained by the Board, its agent or the Attorney General pursuant to N.J.S.A. 45:1-18 shall remain confidential and shall not be disclosed unless so ordered by a court of competent jurisdiction, the appropriate licensing board or the Office of Administrative Law in a contested case.

13:45C-1.6 Maintenance of and access to statements, records or other information that is subject to a privilege declared unavailable

(a) Any statements, records or other information which may be subject to any privilege declared unavailable in this subchapter shall be maintained in a secure place and manner by:

1. The evidence custodian within the Division of Consumer Affairs, Enforcement Bureau;

2. The professional or occupational licensing board and the committee or other subunit of a board or committee located within the Division which has a direct connection with, or a need for access to, the matter to which the statements, records or other information pertain; or

3. A Deputy Attorney General.

(b) Except as may be otherwise ordered as provided in the subchapter, access to statements, records or other information shall be afforded only to employees of the Attorney General, the Enforcement Bureau, or the Board or other subunit of the Division having a direct connection with, or a need for access to, the matter to which the statement, records or other information pertain.

(c) The statements, records or other information shall be retained only for the period of time during which an investigation remains open or until the completion of all administrative or judicial proceedings relating thereto, at which time they shall be returned to the licensee or other person from whom they were obtained. In the absence of such licensee or other person, the statements, records or other information shall be returned to the patient, where appropriate.